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IN THE

Supreme Court of the United States

October Term, 1995

ROYCE LABORATORIES, INC.

Petitioner,

vs.

BRISTOL-MYERS SQUIBB COMPANY,
And E.R. SQUIBB & SONS, INC.,

Respondents,

On Petition For Writ Of Certiorari
To The United States Court Of Appeal
For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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89 pp

QUESTION PRESENTED

On June 8, 1995, the Uruguay Round Agreements Act ("URAA") took effect, which *inter alia* grants a statutory license authorizing non-patentees to make commercial use of products subject to patents whose terms were extended by reason of the URAA. On its face, the statute applies to all such extended patents. The question presented is:

Did the United States Court of Appeals for the Federal Circuit err when it held that as a matter of law, generic drug manufacturers cannot qualify for the URAA statutory license with regard to pharmaceutical patents whose terms have been extended by URAA?

LIST OF PARTIES TO THE PROCEEDING

PURSUANT TO RULES 14(1)(b) AND 29.6

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Petition for Writ of Certiorari.

LIST OF PARTIES PURSUANT TO RULE 29.6

Petitioner Royce Laboratories, Inc. does not have any parent companies or subsidiaries.

TABLE OF CONTENTS

QUESTION PRESENTED i

LIST OF PARTIES TO THE PROCEEDING PURSUANT TO RULES 14(1)(b) AND 29.6 ii

LIST OF PARTIES PURSUANT TO RULE 29.6 ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES vi

OPINIONS BELOW 1

JURISDICTION 1

STATEMENT OF THE CASE 2

INTRODUCTION 2

1. THE INTERNATIONAL AGREEMENT AND STATUTE AT ISSUE 3

a. GATT Required An Extension of United States Patent Terms 3

b. Transitional Compulsory Licenses Are Authorized 4

c. United States Implementation of the Transitional License Provisions 5

2. THE PROCEDURAL ISSUE -- THE HATCH-WAXMAN ACT 10

3. ROYCE'S CAPTOPRIL ANDA 13

4. THE DISTRICT COURT PROCEEDINGS . . 16

5. THE DECISION OF THE FEDERAL CIRCUIT 17

REASONS FOR GRANTING THE WRIT 18

CONCLUSION 26

APPENDIX

A. Opinion of the United States Court of Appeals for the Federal Circuit (November 1, 1995) A-1

B. Order of the United States Court of Appeals for the Federal Circuit Respecting Oral Argument (September 15, 1995) A-21

C. Order of the United States Court of Appeals for the Federal Circuit Respecting Briefing Schedule (September 1, 1995) A-23

D.Order of the United States Court of Appeals for the Federal Circuit Respecting Briefing Schedule (September 1, 1995) A-24

E. Order of United States District Court for the Southern District of Florida, Miami Division, Granting Defendant's Motion To Dismiss And Dissolving Statutory Injunction Against Food & Drug Administration Approval Of Defendants Abbreviated New Drug Application For

Captopril (August 24, 1995) A-27

F. Order of United States District Court for the Southern District of Florida, Miami Division, Setting Expedited Briefing Schedule On Defendant's Motions To Dismiss And To Lift The Statutory Injunction Against Food & Drug Administration Approval of Defendant's Abbreviated New Drug Application For Captopril (August 14, 1995) A-41

G. Relevant Statutes A-43

H. Articles 14 and 70 of Agreement on Trade-Related Aspects of Intellectual Property Rights A-50

TABLE OF AUTHORITIES

Cases:

Ashland Fire Brick Co. v. General Refractories Co.,
27 F.2d 744 (6th Cir. 1928) 6

Eli Lilly Co. v. Medtronic, Inc.,
496 U.S. 661 (1990) 12, 17, 25

Gerhardt v. Kinnaird,
162 F.Supp. 858 (E.D. Ky. 1958)), ... 6

Merck v. Danbury Pharmacal Inc., 873 F.2d 418
(Fed. Cir. 1989), affirming 694 F. Supp. 1
(Dist. Del. 1988) 24

Sony Corp. v. Universal City Studios Inc.
464 U.S. 417 (1984) 19

White v. Fafnir Bearing Co., 263 F.Supp. 788
(D. Conn. 1966) *aff'd* 389 F.2d 750 (2d Cir. 1968) . . 6, 22

INTERNATIONAL AGREEMENTS

Agreement on Trade-Related Aspects of Intellectual
Property Rights 2, 4, 6

Berne Convention for the Protection of Literary and
Artistic Works 5

General Agreement on Tariffs and Trade . . . . Passim

Multilateral Convention for the Protection of Producers
of Phonograms Against Unauthorized Duplication of
Their Phonograms 5

Statutes And Regulations:

21 U.S.C. 355(b)(1) 13

21 U.S.C. 355(j)(2)(A)(vii)(III), (IV) 11

21 U.S.C. 355(j)(4)(B)(iii) 11, 12, 16, 23

21 U.S.C. 357 13

28 U.S.C. 1254(1) 1

35 U.S.C. 152(c) 2

35 U.S.C. 154(a)(2) 6

35 U.S.C. 154(c) 6, 7

35 U.S.C. 154(c)(1) 8, 13, 20

35 U.S.C. 154(c)(2) 8

35 U.S.C. 154(c)(3) 7, 19

35 U.S.C. 252 22

35 U.S.C. 271(a) 19, 20

35 U.S.C. 271(e)(1) 9, 15

35 U.S.C. 271(e)(2) 12, 15, 16

35 U.S.C. 271(e)(4)(A) 8

35 U.S.C. 271(e)(4)(A) 12, 16, 22

35 U.S.C. 283 8

35 U.S.C. 284 8

35 U.S.C. 285 8

Drug Price Competition and Patent Term Restoration Act, (the "Hatch-Waxman Act") Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. 355 and 35 U.S.C. 271(d) - (h)) 10

Uruguay Round Agreements Act ("URAA"), Pub. L. No. 103-465, 108 Stat. 4809 (1994) 2

221 C.F.R. 314.94(a)(12)(v) 13

21 C.F.R. 314.105(b)(1)(iv) 12

Other Sources:

139 Cong. Rec. 1710 (July 1, 1993) 5

141 Cong. Rec. S. 6494 (May 11. 1995) 9

Burchfiel, *GATT Legislation Changes Patent Term*, 77 J.Pat. & Trademark Off. Soc'y, 222 (March 1995) . . . 6

Process Patents Amendments Act of 1987, S.Rep. 100-83, Committee on the Judiciary, 100th Cong., 1st Sess. 47 (June 23, 1987) 10

PETITION FOR WRIT OF CERTIORARI

Royce Laboratories, Inc. respectfully petitions for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the Court of Appeals, which is not yet reported, is reproduced beginning at Appendix page A-1 The opinion and order of the district court, which is not yet officially reported, is reproduced beginning at Appendix page A-27

JURISDICTION

The judgment of the Court of Appeals was entered on November 1, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1). The Jurisdiction of The district Court Rested on 28 U.S.C. 1338(a)

STATEMENT OF THE CASE

INTRODUCTION:

This expedited proceeding[1] brings to this Court, for the first time, issues arising out of recent Congressional legislation implementing the United States' participation in the multi-national agreement known as the General Agreement on Tariffs and Trade ("GATT"). A significant aspect of GATT is the "Agreement on Trade-Related Aspects of Intellectual Property Rights" ("TRIPS").[2] United States participation in the latest GATT Agreement, including TRIPS, was implemented by the President's signing, on December 8, 1994, of the Uruguay Round Agreements Act ("URAA"), Pub. L. No. 103-465, 108 Stat. 4809 (1994). The new legislation includes a statutory license provision authorizing non-patentees to make commercial use of products subject to patents whose term has been extended by URAA. 35 U.S.C. 152(c).

1 The action for patent infringement was filed in the district court on August 4, 1995. Pursuant to an order of the court, proceedings were expedited, A-41, and the District Court entered its judgement dismissing the Complaint on August 24, 1995. A-27 An appeal was taken on August 25, 1995, Fed. Cir. Appendix A0358-59, and immediately upon docketing of the Appeal, a further Order expediting proceedings was entered by the United States Court of Appeals for the Federal Circuit. A-23-24 Oral argument was held in the Court of Appeals on October 11, 1995, and the decision below was rendered on November 1, 1995. A-1

2 The latest round of GATT created the "Final Act Embodying The Uruguay Round of Multilateral Trade Negotiations" signed by the United States and over one hundred other nations on April 15, 1994. The Final Act includes an agreement establishing the World Trade Organization ("WTO"), and various Annexes. The TRIPS Agreement is included as Annex 1C to the WTO Agreement, comprising 73 Articles relating to intellectual property rights.

The United States Court of Appeals for the Federal Circuit held below that as regards pharmaceutical patents whose terms have been extended, generic drug manufacturers are not eligible for the statutory license because, despite URAA, they are prevented from obtaining approval for their products from the United States Food and Drug Administration prior to the expiration of the extended patent term. This decision will affect the marketing status of some one hundred drug products, and will delay the approval of an estimated 800 hundred Abbreviated New Drug Applications on file with the Food and Drug Administration ("FDA"). Aside from the injury to petitioner Royce Laboratories, the decision of the lower court will also result in the imposition of billions of dollars of additional costs to American consumers, as well as federal, state, and private third-party reimbursement plans. Royce Laboratories, Inc. has therefore promptly brought this matter before the Court for review, by way of the instant Petition for a Writ of Certiorari.

1.THE INTERNATIONAL AGREEMENT AND STATUTE AT ISSUE:

a.GATT Required An Extension of United States Patent Terms

Section 5 of the TRIPS Agreement sets forth the obligations of the signatory nations with regard to patent rights. Previously, U.S. patents had a term running seventeen years from the date of the patent grant. Under TRIPS Article 33, the patent term granted by member states may not end before the expiration of a period of twenty years, counted from the filing date. As a GATT/TRIPS signatory, the United States undertook to enact enabling legislation to bring its patent and other intellectual property laws into conformance with the GATT provisions.

b. Transitional Compulsory Licenses Are Authorized

The TRIPS provisions have the effect of extending the terms of patents which are in existence on the date that the member states' enabling legislation takes effect. The drafters of the TRIPS Agreement recognized, however, that the extension of patent terms and other intellectual property rights under the Agreement might unfairly impact upon already existing, and previously planned, activities of various parties in the member states. Article 70 of TRIPS was therefore enacted to protect against such unfairness. Specifically, Article 70(4) provides that as regards "acts" concerning protected subject matter, which become infringing under a member state's implementing legislation, the member may provide for transitional provisions to allow such activity to continue, subject to a requirement for the payment of equitable remuneration.[3] A-52-53

The "equitable remuneration" system as applied to intellectual property rights is a well known concept in international law. The term equitable remuneration is used and applied where intellectual property rights are made subject to a statutory license in favor of parties other than the right holder. For example, in 1988 the

3 Article 70(4), which is the antecedent, authorizing provision of the URAA sections at issue in this case, provides as follows:

> In respect of any acts in respect of specific objects embodying protected subject matter which became infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

United States joined the updated *Berne Convention for the Protection of Literary and Artistic Works.* The Berne Convention authorizes signatories to impose compulsory license requirements so long as the authors' right to at least obtain equitable remuneration is not interfered with. Berne Convention Article 11bis. Similarly, the United States is a signatory to the *Multilateral Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms.* Article 6 of that Convention provides that no compulsory licenses may be granted by any participating country unless the duplication made under the license gives rise to an equitable remuneration to the rights holder.

Congress has often had occasion to consider such international agreements and during one debate prior to Congressional consideration of URAA, the concept of equitable remuneration was described as "a polite term for compulsory licensing."[4] TRIPS Article 14(4) also makes another reference to this well known "system of equitable remuneration" with regard to the rental of phonograms. A-51 It is therefore beyond dispute that the provisions of TRIPS Article 70(4), which authorizes an equitable remuneration system for transitional patents extended by the GATT Agreement, A-52-53 is specifically intended to permit a statutory license system with regard to such patents.

c.United States Implementation of the Transitional License Provisions

The enactment of URAA on December 8, 1994 implemented the United States' participation in GATT, and the TRIPS Agreement. As required by the Multi-

4 139 Cong. Rec. 1710 (July 1, 1993) (remarks of Representative Hughes).

lateral Agreement, Congress amended the Patent Code to provide that patent terms would thereafter run for a period of twenty years from the time of initial filing of the application. 35 U.S.C. 154(a)(2). With regard to patents in effect six months after the date of enactment (*i.e.*, June 8, 1995), Congress elected to include in URAA a transitional statutory license provision, as authorized by TRIPS Article 70(4). See 35 U.S.C. 154(c).[5] It was immediately recognized that by implementing an equitable remuneration system, the "statute thus establishes a compulsory license with respect to the extended patent right." Burchfiel, *GATT Legislation Changes Patent Term*, 77 J.Pat. & Trademark Off. Soc'y, 222 (March 1995).

Although the ruling below has the effect of excluding generic drug manufacturers from the benefits of this statutory license, no such exclusion can be found either in TRIPS, or the URAA itself. The "equitable remuneration" system as codified by Congress at 35 U.S.C. 154(c) on its face, applies to all extended patents as follows:

> (1)DETERMINATION. -- The Term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

5 The essential elements of 35 U.S.C. 154(c) in terms of allowing for the continuation of otherwise infringing acts appears to be modeled on the Patent Code's provisions relating to re-issue patents, found in 35 U.S.C. 252. Those provisions have long been held to be in the nature of a license. *See White v. Fafnir Bearing Co.*, 263 F.Supp. 788, 810 (D. Conn. 1966), (citing *Ashland Fire Brick Co. v. General Refractories Co.*, 27 F.2d 744, 746 (6th Cir. 1928), and *Gerhardt v. Kinnaird*, 162 F.Supp. 858 (E.D. Ky. 1958)), *aff'd* 389 F.2d 750 (2d Cir. 1968).

(2) REMEDIES. -- The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which--

(A) were commenced or for which substantial investment was made before the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) REMUNERATION.-- The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

35 U.S.C. 154(c). A-43

URAA thus indicates that for all of the transitional patents covered by 154(c)(1) during the so-called Delta period, Congress clearly intended that the only remedy a patent holder could assert with regard to the transitional period, was "equitable remuneration," to be determined if necessary, in an action brought under Chapters 28 and 29 of the Patent Code. Congress, in Section 154(c)(2), specifically barred the remedies of injunction, damages and attorneys fees, as broadly defined at 35 U.S.C. 283, 284, and 285.[6] In addition, 154(c)(2) states that previously-commenced acts, which "became infringing" by reason of the URAA, (or acts for which substantial investment was made before June 8, 1995) could be continued during the Delta period, thereby making it crystal clear that qualifying competitors of the patent holder would be able to market and sell their products during the transition period.

6 In so doing, Congress removed all of the substantive remedies otherwise applicable to patent infringement. Section 283, for example, provides for injunctive relief "in accordance with the principles of equity to prevent the violation of any right secured by patent." URAA makes not only 283 inapplicable, but provides that the *remedies* of 283 are not available to the patent holder. Injunctive relief, whatever form it takes under the patent laws, is thus precluded by URAA. In the proceedings below, Bristol argued that the "remedy" of 35 U.S.C. 271(e)(4)(A) -- clearly a form of injunction against FDA approval of an Abbreviated New Drug Application -- is not limited by URAA. There is no basis for engrafting such an exception onto the broad limitations of remedies set forth in URAA, and the Court of Appeals did not premise its decision on such an interpretation.

The most obvious intended beneficiary of the statutory licensing system was the generic drug industry. Over one hundred pharmaceutical patents, involving many billions of dollars in sales, fall within the transitional provisions. *See* 141 Cong. Rec. S. 6494 (May 11. 1995) (Remarks of Sen. Pryor). In fact, since the adoption of TRIPS and the URAA, no industry other than the generic drug industry has emerged as being potentially affected by the equitable remuneration system.[7] Also, this is not the first time that Congress, while amending the patent laws, has seen fit to enact transitional provisions relating to pending competitive marketing plans regarding patented products. In 1988, after several years of deliberation, Congress enacted the Process Patent Amendment Act which included a general transition provision, primarily because of a concern for adverse effects on the generic drug industry:

> The generic companies contended that if their supply of raw materials from overseas sources is reduced by process patent infringement suits, then the goals of P.L. 98-417 would be undermined. With the protections built into the substitute approved by the Committee, the generic

7 The generic drug industry is, in fact, the only industry in the United States wherein substantial investments in patented products are routinely made long in advance of patent expiration. In enacting URAA, Congress undoubtedly was aware that under 35 U.S.C. 271(e)(1), generic drug companies may engage in the necessary testing required to prepare for ANDA applications, without thereby infringing a patent holder's rights. It is thus typical for ANDA applicants to expend huge sums before FDA approval is actually obtained in anticipation of eventual patent expiration. The Congressional election to invoke the transitional "equitable remuneration" provisions of GATT most logically were directed toward protecting the generic drug industry.

> pharmaceutical industry now supports S. 1200. It should be recognized, in particular, that the grandfather clause gives an exception for the many new generic medicines that have been approved or whose applications have been submitted to the FDA during the period between enactment of P.L. 98-417 (signed into law on September 24, 1984) and May 15, 1987.

Process Patents Amendments Act of 1987, S.Rep. 100-83, Committee on the Judiciary, 100th Cong., 1st Sess. 47 (June 23, 1987).

In light of this background, no serious argument was ever advanced below that Congress actually intended the generic drug industry to be excluded from the statutory license provisions of URAA.

2. THE PROCEDURAL ISSUE -- THE HATCH-WAXMAN ACT

Despite the apparent applicability of the URAA licensing to generic drugs, the issues in this case arise as a result of the collateral, and seemingly unrelated, fact that the marketing of prescription generic drugs in the United States requires advance FDA approval. In 1984, after several years of debate, Congress passed the Drug Price Competition and Patent Term Restoration Act, (the "Hatch-Waxman Act") Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. 355 and 35 U.S.C. 271(d) - (h)), for the purpose of fostering the earliest possible availability of generic drug products. This was accomplished by codifying an Abbreviated New Drug Application ("ANDA") procedure by which generic drug manufacturers must submit an application to FDA, so that the Agency can determine that the generic drug is,

in fact, equivalent to a previously approved "pioneer" drug product.

The Hatch-Waxman statute also provides a mechanism for either (1) deferring FDA approval until after the patent for the underlying drug product has expired, or (2) allowing an early challenge to the applicability of a given patent, with the timing of FDA approval then being dependent upon the outcome of judicial proceedings. 21 U.S.C. 355(j)(4)(B)(iii). In this regard, Hatch-Waxman requires patent holders to list their patents with FDA, and generic drug applicants must submit one of four certifications respecting the patent status of the drug product which is the subject of their ANDA. The particular certification submitted will procedurally determine how the eventual effective date of the ANDA approval is established.

Two of these certifications are relevant here, and are known as the "paragraph III" and "paragraph IV" certifications. 21 U.S.C. 355(j)(2)(A)(vii)(III), (IV). A paragraph III ANDA certification lists the patent owner's FDA-listed expiration date for the reference drug's patent. 21 U.S.C. 355(j)(2)(A)(vii)(III). Where such a certification is made in an ANDA, the application may only be approved upon patent expiration. 21 U.S.C. 355(j)(4)(B)(iii). A "paragraph IV" certification is used by an ANDA applicant to assert a right to engage in the acts of commercial manufacturing, marketing, and sale of the reference drug product prior to the expiration date of the relevant patent. *See* 21 U.S.C. 355(j)(2)(A)(vii)(IV).

An ANDA applicant who submits a paragraph IV certification is required by statute to give notice to the patent holder of such filing, together with a statement explaining the applicant's reasons for asserting the right to market prior to the expiration of the patent. The statute directs that the application is to be made effective immediately, unless the patent holder commences a patent infringement action against the ANDA applicant within

forty-five days of receipt of the notice. 21 U.S.C. 355(j)(4)(B)(iii). If such a patent infringement action is timely commenced, FDA approval of the ANDA is to be deferred, pending the outcome of the litigation, up to a maximum of thirty months. *Id.* The Court is also authorized to modify the statutory bar to approval in appropriate circumstances. *Id.*

Under FDA regulations implementing the Hatch-Waxman Act, a paragraph IV certification is properly used to assert that the patent is either "invalid, unenforceable, or will not be infringed." 21 C.F.R. 314.105(b)(1)(iv). If ensuing litigation results in a determination in favor of the ANDA applicant, FDA is authorized to immediately approve the ANDA. If the assertions contained in a paragraph IV certification are "in error," the ANDA applicant's attempt to obtain commercial marketing approval prior to the patent expiration is deemed "an artificial and technical act of infringement," under 35 U.S.C. 271(e)(2), and the patent holder is entitled to a court order directing that the final regulatory approval be withheld until the patent expiration date. 35 U.S.C. 271(e)(4)(A). *See generally Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

The inter-relation of the URAA and the Hatch-Waxman Act inherently arises from the fact that an ANDA applicant must obtain FDA approval before it can commercially market its product pursuant to the statutory license provisions of URAA. [8] FDA regulations provide that licensees can obtain ANDA approval by filing a paragraph IV certification, to show the nature and extent of their license. 21 C.F.R. 314.94(a)(12)(v). [9] The issue presented here is whether the paragraph IV certification procedures can be used to implement the statutory license and equitable remuneration system under URAA.

3. ROYCE'S CAPTOPRIL ANDA:

Respondents own the rights to United States Patent No. 4,105,776 ("the '776 patent"), which claims the drug Captopril, marketed under the brand name "Capoten." Captopril is an important and highly profitable drug used for the treatment of life-threatening heart disease. Prior to enactment of the URAA, the Captopril patent was scheduled to expire on August 8, 1995. By reason of the patent term extension of the URAA, 35

8 However, not all generic drug products are subject to the ANDA patent certification procedure. Antibiotic drug products, for example, are not covered by the Hatch-Waxman provisions. *See* 21 U.S.C. 357. The patent certification provisions are also inapplicable to full New Drug Applications. 21 U.S.C. 355(b)(1). The ruling of the Federal Circuit thus carves out ANDA pharmaceutical products for the singular distinction of being the only pharmaceuticals subject to FDA regulation which do not qualify for the URAA statutory license.

9 Bristol's wholly owned subsidiary, Apothecon Inc., obtained such an ANDA approval based upon a paragraph IV certification which became effective because Bristol obviously did not commence a patent infringement suit after Apothecon filed its paragraph IV certification. The Apothecon product has not been marketed to date.

U.S.C. 154(c)(1), Bristol's Captopril patent term was extended until February 13, 1996.

Petitioner Royce Laboratories, Inc. manufactures and markets various "generic" prescription drug products. The FDA ANDA approval process referred to above is rigorous and time consuming. Consequently, long before the enactment of URAA, Royce had invested approximately one million dollars in preparation for the marketing of Captopril commencing on August 9, 1995. In early 1992, Royce commenced its research and development program to find a bio-equivalent solid oral dosage form of the drug Captopril. In 1993, Royce conducted the required in-vitro and in-vivo bio-equivalence studies for the purpose of a contemplated ANDA submission. The ANDA itself was submitted on January 3, 1994, and was continuously and diligently pursued thereafter. On March 31, 1995, FDA issued a "tentative approval" for the Royce Captopril ANDA. [10] The approval was denominated "tentative" because the original '776 patent had not expired as of the date of the approval letter. Under FDA regulations, the "tentative approval" (absent URAA) would have become final on August 8, 1995, the original expiration date of the '776 patent.

Royce's purpose in seeking ANDA approval at all times has been to obtain such approval for marketing on August 9, 1995. The ANDA originally contained a paragraph III certification, referring to the August 8, 1995 patent expiration date, which had been listed by Bristol with FDA under the Hatch-Waxman procedures.

10 Tentative approval by FDA signifies that all of the scientific and technical requirements for approval have been met. The only remaining question is the fixing of the effective date.

Royce's ANDA submission was thus at first a totally "non-infringing" act, expressly allowed by 35 U.S.C. 271(e)(1). Royce's ANDA, however, seeking approval after August 8, 1995, became technically infringing by the enactment of URAA, which extended the expiration date for the '776 patent. [11]

In order to proceed to finalize its Captopril ANDA, in May 1995 Royce wrote to Bristol, setting forth Royce's qualifications for the URAA statutory license, and offering to pay equitable remuneration. Bristol responded by refusing to negotiate equitable remuneration, and by denying that Royce had any rights under URAA. Thereafter, on June 15, 1995, Bristol amended its patent date listing with the FDA, setting forth the URAA-extended expiration date of February 13, 1996. On June 26, 1995 Royce filed a paragraph IV certification, as an amendment to its pending ANDA, which asserted that Royce *continued to seek approval on August 9, 1995,* by reason of Royce's statutory license rights under URAA. [12] The required statutory notice, with a full explanation, was then given to Bristol. Royce's position was that the eventual sale by Royce of Captopril during the Delta period would not infringe Bristol's rights because Royce was entitled to make such sales under URAA. Bristol then commenced an action for patent infringement in the

11 Under 35 U.S.C. 271(e)(2), it is a technical act of infringement to submit an ANDA if the "purpose" is to obtain approval prior to the expiration date of the patent.

12 Royce's certification under the applicable FDA regulations was thus a combination of an assertion of non-infringement based upon the URAA license, and the unenforceability provisions of URAA in terms of the limitation of remedies.

District Court within the statutory forty-five day period. [13] FDA approval of Royce's ANDA was then temporarily suspended by reason of the "statutory bar" of 21 U.S.C. 355(j)(4)(B)(iii).

4. THE DISTRICT COURT PROCEEDINGS:

Bristol's Complaint did not present any of the traditional allegations of patent infringement. The sole gravamen of the complaint is that Royce has filed an ANDA which, by reason of the URAA patent term extension, had become an application which seeks approval prior to the expiration of the Captopril patent. Asserting that seeking approval for such purpose constituted infringement under 35 U.S.C. 271(e)(2), Bristol alleged that it was entitled to an order under 35 U.S.C. 271(e)(4)(A), preventing FDA approval of Royce's Captopril ANDA until February 13, 1996.

Shortly after the action was commenced, Royce moved for an Order "lifting the statutory injunction" against approval of Royce's ANDA, [14] and further asking for an Order dismissing the Complaint. Royce's motion was based on a showing that it qualified for the statutory license under URAA, and that accordingly, there was no reason to block FDA approval. The District Court, in a carefully reasoned opinion, found that Bristol's claim of an automatic right to bar Royce's ANDA approval because of the alleged technical act of infringement under

13 In light of the obvious urgency of resolving the issues before August 8, 1995, Royce had asked Bristol to file an action not later than July 10, 1995. Bristol rejected this request, and waited almost the full forty-five days before commencing the action.

14 As a matter of terminology, the Federal Circuit preferred to use the term "statutory bar" to describe this provision. *See* A-9, n. 2.

271(e)(2) was unfounded. Based upon this Court's decision in *Eli Lilly Co. v. Medtronic, Inc.*, the Court analyzed the relevant statutory provisions and held that the proper issue in an infringement action following a paragraph IV certification was not whether a technically infringing ANDA had been submitted, but whether the ANDA applicant was entitled to market its product in the event of FDA approval. Finding that Royce qualified for the statutory license under URAA, the Court concluded that Royce's paragraph IV certification was correct, and not in error. The District Court therefore lifted the statutory bar to FDA approval of Royce's ANDA, and further directed that the Complaint be dismissed for failure to state a cause of action. [15] Bristol's appeal followed.

5. THE DECISION OF THE FEDERAL CIRCUIT:

After an expedited appellate review, the Federal Circuit reversed. Although agreeing with Royce and the District Court that the proper issue was whether Royce's paragraph IV certification was in error, the Federal Circuit analyzed the Hatch-Waxman provisions in such a way as to find a technical error in Royce's certification. Characterizing the URAA authorization for marketing as a "safe harbor," the appeals court found that as a matter of semantics, under URAA "infringement is still infringement." Noting the absence of any indication that Congress actually intended to exclude ANDA products, A-14, n.4, the Federal Circuit decision holds that never-

15 It is to be noted that Bristol, in its complaint, did not even allege that Royce did not meet the requirements for a statutory license under URAA. Bristol also did not seek equitable remuneration, and made no mention of the fact that Royce had offered to pay equitable remuneration in order to exercise its statutory license rights.

theless, the URAA only limits remedies, and that commercial sales, under the equitable remuneration system, would constitute an act of infringement. Accordingly, the Federal Circuit held that Royce had incorrectly certified to FDA that its eventual sales of Captopril would not "infringe." A-19

The decision below does not dispute that Bristol's remedies against Royce would be limited to equitable remuneration under URAA if Royce were to actually sell Captopril after August 8, 1995. The Court, in effect held, however, that this issue can never be reached because Bristol was entitled to preemptively prevent such sales by blocking Royce's ANDA under the Hatch-Waxman paragraph IV certification procedures. The Court of Appeals therefore directed the District Court to reinstate Bristol's Complaint, and to grant Bristol an Order directing FDA not to approve Royce's ANDA until February 13, 1996. A-19-20

REASONS FOR GRANTING THE WRIT

For the first time in the history of United States patent law, a court has held that activity expressly authorized by Congress is to be categorized as "infringement." Furthermore, this interpretation has been retroactively imputed to Congress which, under the Hatch-Waxman Act, is now held to have intended that an ANDA holder cannot invoke the paragraph IV certification procedure to claim a statutory license right, because the practice of such license would constitute "infringe-

ment."[16] This Court has previously emphasized that the analysis of infringement issues under the patent laws must in the first instance be premised on the concept of infringement as expressly defined by statute. *Sony Corp. v. Universal City Studios Inc.* 464 U.S. 417, 440 (1984). Here, the Federal Circuit has totally failed to explain how Royce's authorized sales of generic Captopril under URAA would fall within the patent laws' definition of infringement.

Title 35 U.S.C. 271(a) provides:

> Except as otherwise provided in this title, whoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.

There is no question but that Royce's eventual sales under URAA are authorized by statute. First, Royce's submission of an ANDA, in the statutory language, is an "act" which was commenced before the effective date of June 8, 1995, and which became infringing by reason of the URAA amendments. *See* 35 U.S.C. 154(c)(1). URAA expressly states that such action "may be continued" upon payment of equitable remuneration. *See* 35 U.S.C. 154(c)(3). Furthermore, the District Court found that Royce had made a "substantial investment" in

16 Inasmuch as the URAA provisions with regard to equitable remuneration appear to have their primary, if not exclusive, applicability to the generic drug industry, the ruling below in effect amounts to a repeal of the statutory license granted by URAA.

advance of the effective date, and for that reason was qualified to "continue" its acts in furtherance of the investment, under the URAA provisions. A-35 n.7. In the terminology of the basic definition of infringement under 35 U.S.C. 271(a), Royce's sales during the delta period are thus expressly authorized by statute. Such authorized conduct cannot possibly constitute infringement under the statutory definition. [17]

It is clear that the Court of Appeals held that Royce could be considered an infringer even though its actions were authorized under URAA:

> As noted above, Royce contends that distribution of its generic version of Captopril during the delta period would not constitute infringement of the '776 patent. It bases this contention on the same reasoning that the District Court used: the URAA authorizes the sale of products that are covered by the claims of a valid patent. Royce argues that such an "authorized" sale cannot constitute infringement. Put another way, Royce claims that when the URAA says that particular conduct "may continue," it means that the conduct is not infringement. Consequently, Royce asserts, its paragraph IV certification was correct. Therefore, the Hatch-Waxman Act does not bar approval of its ANDA.
>
> A-14

17 In addition, the definition of infringement begins with the proviso "except as otherwise provided in this title." The URAA provisions are obviously part of the same title, i.e., the patent code. The authorization for sales under URAA thus overrides any possible claim of a finding of "infringement" under Section 271.

The statutory scheme does not say, as Royce argues and as the District Court held, "If normally you would infringe, you do not infringe during the Delta period." Rather, it says, "If normally you would infringe, you also infringe during the Delta period. The difference is that, for infringement during the Delta period, you are not subject to the traditional remedies for patent infringement. Instead, you pay the patent owner an equitable remuneration."

A-15-16

Contrary to Royce's argument and the holding of the district court, we do not believe that the URAA makes infringing conduct non-infringing during the Delta period. It merely provides that infringing conduct will not give rise to the entire panoply of traditional statutory remedies for patent infringement. Such conduct will give rise only to the limited remedy of equitable remuneration.

A-15

We hold that the URAA does not convert Royce's sale of generic Captopril during the Delta period into a non-infringing activity. Thus, Royce's paragraph IV certification to the contrary is incorrect. This means that Bristol is entitled to the Hatch-Waxman Act remedy that is "triggered" by the filing of an incorrect paragraph IV certification. That remedy is an order from the district court that the effective date of any approval of Royce's ANDA be not earlier than February 13,

Royce's ANDA be not earlier than February 13, 1996, the expiration date of to '776 patent.

A-19

The ruling of the Court of Appeals converts the paragraph IV procedure into a trap which prevents otherwise qualified parties from invoking a statutory license such as that found in the URAA. The Court of Appeals notes that URAA makes no reference to the Hatch-Waxman Act. The Court of Appeals ignores the fact, however, that there is nothing in the Hatch-Waxman Act which suggests that generic applicants are to be deprived of the ability to exercise a statutory license. [18] The United States trade representative who negotiated the TRIPS provisions as part of the GATT WTO Agreement, has stated unequivocally that the equitable remuneration provisions were intended to apply to all extended patents, without any exception as regards the generic drug industry. A-30

The fundamental error in the Court of Appeals ruling is that in interpreting the paragraph IV certification procedure, the Federal Circuit has placed the proverbial cart before the horse. Hatch-Waxman granted a

18 The decision of the Court of Appeals will have a wide impact with regard to any other statutory licenses. For example, under 35 U.S.C. 252, provision is made for permitting non-patentees to engage in the commercial marketing and exploitation of certain products covered by re-issue patents. The courts have long held that these statutory provisions are in the nature of a license. See White v. Fafnir Bearing Co., supra. Under the Court of Appeals analysis, ANDA applicants who had already been approved could qualify to market their products under 35 U.S.C. 252. However, an unapproved ANDA would be blocked from approval because there, as here, the Court of Appeals would semantically find that "infringement is still infringement" and that only remedies have been limited. The Court of Appeals analysis would therefore clearly lead to absurd results.

remedy to patent holders under 35 U.S.C. 271(e)(4)(A) to deal with circumstances where the ANDA applicant was not entitled to sell its product. Here, the reverse is true. The Court has elevated form over substance in making a finding that the ANDA applicant cannot eventually sell its product for the sole reason that it cannot obtain an FDA approval.

Looking at the Hatch-Waxman procedures as a whole, the ruling of the Federal Circuit cannot withstand scrutiny. If, Bristol had commenced its action against Royce after the forty-five day period, under the statute, Royce's ANDA would have been approved. 21 U.S.C. 355(j)(4)(B)(iii). Royce would then have been able to sell generic Captopril under URAA, and Bristol's remedies would have been duly limited. Similarly, if time constraints had been different, and a patent litigation had been commenced against Royce, but not concluded for thirty months, the statute would once again have directed FDA to approve the ANDA. *Id.* In both of these cases, Royce would have been able to sell its generic Captopril

because Congress gave it that right under URAA. There is, therefore, no reason to believe that Congress intended the Hatch-Waxman procedures as a bar to a generic applicant's ability to claim a statutory license.

The same conclusion flows inescapably from the general practice under the paragraph IV certification procedures with regard to unenforceable patents. In circumstances where a claim of inequitable conduct arises, ANDA applicants can nevertheless make a paragraph IV certification, claiming a right to market. *See Merck v. Danbury Pharmacal Inc.*, 873 F.2d 418, Fed. Cir. 1989, affirming 694 F. Supp. 1 (Dist. Del. 1988). [19] The same is true in the instant case. URAA has made the Bristol patent unenforceable as against Royce. Specifically, the remedies of 35 U.S.C. 283-285 are made inapplicable. Although Bristol is prevented from obtaining any type of injunction, under law or equity, the Court of Appeals has violated the mandate of URAA by in effect authorizing

19 In *Merck v. Danbury* the infringement action was triggered by an ANDA filing. Despite a technical 271(e)(2) infringement, the Court dismissed the infringement suit after finding that the patent was unenforceable. FDA thereafter promulgated a regulation incorporating unenforceability as one of the factors which, when found by a district court, would lead to ANDA approval:
"Although the agency realizes that courts have, in patent cases, distinguished invalid patents from unenforceable patents, the only court addressing the issue of unenforceable patents in the context of the provisions of section 505 of the act interpreted the phrase 'invalid or not infringed' to include an unenforceable patent. (See Merck v. Danbury Pharmacal, Inc., 694 F.Supp. 1 (D.Del. 1988), aff'd, 873 F. 2d 1418 (Fed. Cir. 1989) (applying section 505 (j) (4) (B) (iii) of the act).) The agency agrees with the court's construction of the act. The alternative interpretation, precluding applicants challenging patents as unenforceable from filing certifications under paragraph IV, would be contrary to Congress' obvious intent in allowing patent challenges under section 505 of the act and would lead to absurd results." 59 Fed. Reg. 50339 (Oct. 3, 1994).

an injunction against FDA approval of Royce's ANDA.[20]

The ruling of the Federal Circuit has thus transformed the procedural provisions of the Hatch-Waxman Act into a substantive independent grant of right to the patent holder. This is directly contrary to this Court's interpretation in *Eli Lilly.*

> That is what is achieved by 271(e)(2) -- the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent. Not only is the defined act of infringement artificial, so are the specified consequences, as set forth in subsection (e)(4).
>
> *Eli Lilly, supra,* 496 U.S. at 678

This Court should therefore grant certiorari to review the ruling of the Court of Appeals, which is contrary to the statutory interpretation of this Court. The TRIPS Agreement was intended to harmonize international intellectual property rights. Now, after the very first U.S. judicial interpretation, the opposite has occurred and harmonization has been prevented. Generic companies based in the United States are prohibited from taking advantage of the TRIPS equitable remuneration system, while foreign countries -- who are not limited by the particular procedures involved in paragraph IV certifications -- are free to implement the statutory license provisions for their citizens.

20 See also note 6 supra.

Thus, several hundred ANDA applications have suddenly been derailed from their proper time schedule as a result of the lower court's ruling. The Federal Circuit has exclusive jurisdiction to hear cases raising these issues, and as a result, all ANDA applicants for the approximately 100 drugs covered by the transitional provisions of URAA will now be bound by the lower court's ruling and therefore unable to file paragraph IV certifications in order to claim their right to market during the Delta period. This petition represents this Court's first, and only, opportunity to address and remedy the issues raised. The ruling of the lower court presents an issue of major and compelling public importance, warranting the Supreme Court's immediate intervention.

CONCLUSION

For the foregoing reasons, it is respectfully requested that the Petition for a Writ of Certiorari should be granted. Upon the hearing of this matter, the Court should reverse the decision of the Court of Appeals by reinstating both the District Court's lifting of the statutory bar to approval of Royce's Captopril ANDA, as well as the judgment dismissing Bristol's complaint.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

95-1502

BRISTOL-MYERS SQUIBB COMPANY and
E.R. SQUIBB & SONS, INC.,

Plaintiffs-Appellants,

v.

ROYCE LABORATORIES, INC.,

Defendant-Appellee.

Robert J. Brookhiser, Howrey & Simon, of Washington, D.C., argued for plaintiffs-appellants. With him on the brief were Robert L. Beachtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, and Donald J. Barrack, Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc., of Princeton, New Jersey.

Milton A. Bass, Bass & Ullman, P.C., of New York, New York, argued for defendant-appellee. With him on the brief were Jacob Laufer and James N. Czaban.

Appealed from: U.S. District Court for the Southern District of Florida

Judge Bandstra

95-1502

BRISTOL-MYERS SQUIBB COMPANY and
E.R. SQUIBB & SONS, INC.,

Plaintiffs-Appellants,

v.

ROYCE LABORATORIES, INC.,

Defendant-Appellee.

DECIDED: November 1, 1995

Before SCHALL, Circuit Judge, COWEN, Senior Circuit Judge, and BRYSON, Circuit Judge.

SCHALL, Circuit Judge.

Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc. (collectively, "Bristol") own United States Patent No. 4,107,776 (the "'776 patent"), which claims the drug captopril. In this action, Bristol appeals from the August 24, 1995 order of the United States District Court for the Southern District of Florida in Bristol-Myers Squibb Co. v. Royce Labs. Inc., ___ F. Supp. ___, No. 95-1682-CIV-DAVIS. In its order, the court granted the motion of Royce Laboratories, Inc. ("Royce") pursuant to

Fed. R. Civ. P. 12(b)(6) to dismiss, for failure to state a claim upon which relief could be granted, Bristol's suit charging Royce with infringement of the '776 patent. The court also granted Royce's motion to set aside the statutory bar against the Food and Drug Administration ("FDA") approving Royce's abbreviated new drug application ("ANDA") for a generic version of captopril. We reverse and remand.

BACKGROUND

I.

Two laws are at issue in this case: The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. 355 (1994) and 35 U.S.C.A. 271(d)-(h) (West Supp. 1995)) (the "Hatch-Waxman Act"); and the Uruguay Round Agreements Act, Pub. L. No. 103-465, 108 Stat. 4809 (1994) (codified as amended at 35 U.S.C.A. 154 (West Supp. 1995)) (the "URAA"). We begin with the statutory scheme.

A. The Hatch-Waxman Act

The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 52-675, 52 Stat. 1040 (1938), (codified as amended at 21 U.S.C. 301 et seq. (1994)) (the "FDCA"), as well as the patent laws, in several important respects. Under the FDCA, the FDA is responsible for determining whether a generic drug product should be approved for sale to the public. 21 U.S.C. 355(a). Pursuant to the Hatch-Waxman Act, a pharmaceutical manufacturer seeking expedited FDA approval to market a generic version of a patented drug may submit an ANDA. 21 U.S.C. 355(j). An applicant submitting an ANDA must certify one of four things: (1) that the drug for which the ANDA is submitted has not been patented (a "paragraph I" certification); (2) that any

patent on such drug has expired (a "paragraph II" certification); (3) the date on which the patent on such drug will expire, if it has not yet expired (a "paragraph III" certification); or (4) that the patent on such drug "is invalid or that it will not be infringed by the manufacture, use, or sale of the new drug" for which the ANDA is submitted (a "paragraph IV" certification). 21 U.S.C. 355(j)(2)(A)(vii)(I)-(IV). When an applicant submits an ANDA that contains a paragraph IV certification, it must give the owner of the relevant patent notice of the certification. 21 U.S.C. 355(j)(2)(B).

The Hatch-Waxman Act provides generally that "[i]t shall not be an act of infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C.A. 271(e)(1). Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement. The statute, referring to an ANDA containing a paragraph IV certification, states: "It shall be an act of infringement" to submit an application under 21 U.S.C. 355(j) "for a drug claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of [the] drug . . . before the expiration of [the] patent." 35 U.S.C.A. 271(e)(2)(A).

If an ANDA contains a paragraph I or a paragraph II certification, and all applicable scientific and regulatory requirements have been met, FDA approval of the ANDA is effective immediately. 21 U.S.C. 355(j)(4)(A), (B)(i). If the ANDA contains a paragraph III certification, and all applicable scientific and regulatory requirements have been met, approval is effective on the patent expiration date stated in the certification. 21 U.S.C. 355(j)(4)(A), (B)(ii).

If the ANDA contains a paragraph IV certification, and all applicable scientific and regulatory requirements have been met, approval of the ANDA "shall be made effective immediately" unless the patent owner brings an action for infringement under 35 U.S.C.A. 271(e)(2)(A) within forty-five days of receiving the notice required by 21 U.S.C. 355(j)(2)(B). 21 U.S.C. 355(j)(4)(B)(iii). The Hatch-Waxman Act further provides that, when a patent owner brings a section 271(e)(2)(A) infringement action, the FDA must suspend approval of the ANDA. Id. The suspension continues -- and the FDA cannot approve the ANDA -- until the earliest of three dates: (i) if the court decides that the patent is invalid or not infringed, the date of the court's decision; (ii) if the court decides that the patent has been infringed, the date that the patent expires; or (iii) subject to modification by the court, the date that is thirty months from the patent owner's receipt of notice of the filing of the paragraph IV certification. 21 U.S.C. 355(j)(4)(B)(iii)(I)-(III); 35 U.S.C.A. 271(e)(4)(A).

Thus, the Hatch-Waxman Act strikes a balance between the interests of a party seeking approval of an ANDA and the owner of a drug patent. On the one hand, the manufacture, use, or sale of a patented drug is not an act of infringement, to the extent it is necessary for the preparation and submission of an ANDA. On the other hand, once it is clear that a party seeking approval of an ANDA wants to market a patented drug prior to the expiration of the patent, the patent owner can seek to prevent approval of the ANDA by bringing a patent infringement suit. While it is pending, such a suit can have the effect of barring ANDA approval for two and a half years.

B. The URAA

President Clinton signed the URAA on December 8, 1994, implementing the participation of the United States in the General Agreement on Tariffs and Trade.

Section 532(c) of the URAA is the provision of the act that is applicable to this case. It provides as follows:

(c) Continuation. --

(1) Determination. -- The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers. [1]

(2) Remedies. -- The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which--

(A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

1 Subsection (a)(2) of the URAA provides that the term of a patent
shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific
reference to an earlier filed application or applications under section 120, 121, or 365(c) of . . . title [35], from the date on which the earliest such application was filed.
35 U.S.C.A. 154(a)(2) (West Supp. 1995).

(3) Remuneration. -- The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

35 U.S.C.A. 154(c). Thus, the URAA creates a limited safe harbor for persons who commenced particular acts, or made substantial investment toward commission of those acts before June 8, 1995 (the date six months after the URAA was enacted), which acts became infringing because of the extension of the patent period by the URAA. Under the URAA's safe harbor provision, a patent owner may not assert the traditional remedies of 35 U.S.C. 283, 284, and 285 (1988) for qualifying acts of infringement committed during the period of a patent's extension (the "Delta" period). See 35 U.S.C.A. 154(c)(2). The patent owner is entitled to an equitable remuneration, however, for such acts. See 35 U.S.C.A. 154(c)(3).

II.

A. Royce's ANDA

As noted above, the '776 patent claims the drug captopril. Captopril, which is commercially marketed under the trademark "Capoten," is used to treat hypertension, heart failure, diabetic nephropathy (kidney disease resulting from diabetes), and left ventricular dysfunction following myocardial infarction. When it was first issued, the expiration date of the '776 patent was August 8, 1995. The URAA, however, extended the term of the patent to February 13, 1996.

Royce planned to begin selling a generic version of captopril after the August 8, 1995 expiration date of the '776 patent. In anticipation of this, it submitted an ANDA to the FDA on June 26, 1994. In its ANDA, Royce included a paragraph III certification stating that the '776 patent would expire on August 8, 1995. After the URAA went into effect, however, the FDA, in a response to a citizen petition, ruled that paragraph IV certifications should be submitted for all generic drugs sought to be sold after the original patent expiration date and before the extended expiration date (i.e., during the Delta period). Royce amended its ANDA to include a paragraph IV certification.

In its paragraph IV certification, Royce did not state that the '776 patent was invalid or that the claims of the patent did not cover Royce's generic captopril. Rather, Royce stated that by manufacturing, using, or selling generic captopril during the Delta period, it would not infringe the '776 patent because it would be operating under the safe harbor of the URAA, meaning the provision of the URAA precluding the remedies of 35 U.S.C. 283-85. Bristol-Myers Squibb Co., No. 95-1682-CIV-DAVIS, slip op. at 5. Upon amending its ANDA to include the paragraph IV certification, Royce gave Bristol the notice required by the Hatch-Waxman Act. See 21 U.S.C. 355(j)(2)(B).

B. Proceedings in the District Court

In due course, after receiving Royce's notice, Bristol brought its action in the district court, charging Royce with patent infringement under 35 U.S.C.A. 271(e)(2)(A). Bristol alleged that Royce had infringed the '776 patent by submitting an ANDA seeking FDA approval to market a generic version of captopril before the expiration of the patent. In view of the fact that Royce neither had challenged the validity of the '776 patent nor had claimed that its generic version of captopril was not

covered by the claims of the patent, Bristol asked the district court to enter an order pursuant to 35 U.S.C.A. 271(e)(4)(A) that the effective date of approval of Royce's ANDA be no earlier than the February 13, 1996 expiration date of the '776 patent. Shortly after Bristol filed its complaint, Royce moved for an order dismissing the complaint and dissolving the statutory bar against FDA approval of Royce's ANDA. Royce also asked the court to make its ANDA effective immediately. [2]

In addressing Royce's motion, the district court noted that infringement under 35 U.S.C. 271(e)(2), through the filing of a paragraph IV certification, is a "somewhat artificial" form of infringement created by the Hatch-Waxman Act. Bristol-Myers Squibb Co., No. 95-1682-CIV-DAVIS, slip op. at 4. Thus, the court posited that the question before it was not "whether Royce's application to use the drug infringes the patent, but rather whether its manufacture, use, [or] sale of the drug infringes the '776 patent." Id. at 6. The court continued by stating that "if the paragraph IV certification is subsequently found by the district court to be correct in that the applicant's use of the drug after FDA approval will not infringe the patent, then there is no longer any 'artificial infringement' of the patent and the patentee has no actionable claim against the ANDA applicant." Id. at 7. The court concluded that Congress's objective in creating section 271 "was to strike a 'careful balance between

2 Royce's filing was styled an "Emergency Motion to Set Aside Injunction and Dismiss Complaint." There was, of course, no injunction in effect. The "injunction" to which Royce was referring was the Hatch-Waxman Act prohibition against approval of Royce's ANDA, which came into effect upon the filing of Bristol's lawsuit. See 21 U.S.C. 355(j)(4)(B)(iii). We believe it more accurate to refer to the "statutory bar" that came into effect when Bristol filed its lawsuit, rather than to speak in terms of an injunction.

the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs.'" Id. at 9 (citing Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50,338 (1994)). The court then stated:

> The only reading of the URAA and the Hatch-Waxman Act that maintains this compromise is that the [URAA] provides the patentees an extended patent term in exchange for allowing the new drug companies to use the patented drug in an otherwise infringing manner as long as they pay equitable remuneration to the patentees for the commercial use. Under this reading of the governing statutes and treaties, Royce's manufacture, use, or sale of the drug within the "safe harbor" provision of the URAA would not infringe the '776 patent.

Id. at 10.

Based upon this reasoning, the court determined that Royce's "paragraph IV certification stating noninfringement is not in error and no longer constitutes an actionable infringement under section 271." Id. Accordingly, the court ruled that, since "there would be no infringing activity by Royce after FDA approval," there was no longer any need to prohibit approval, and therefore Bristol's amended complaint failed to state a claim upon which relief could be granted. Id. at 11. [3]

3 The court declined, however, to direct the FDA to approve Royce's ANDA. In the United States Court of Appeals for the Eleventh Circuit, Royce has filed what it calls a "Petition for Review of Agency Refusal to Issue Approval of Abbreviated New Drug Application." See In re Royce Laboratories, Inc. v. Food and Drug Administration, Case No. 95-5094. In that appeal, Royce argues that the FDA acted improperly by failing to make approval of Royce's ANDA effective on August 24, 1995, the date of the district court's decision in this case.

DISCUSSION

I.

Whether the district court properly granted Royce's motion to dismiss is a question of law that we review de novo. Highland Falls-Fort Montgomery Cent. Sch. Dist. v. United States, 48 F.3d 1166, 1170 (Fed. Cir.), cert. denied, 116 S. Ct. 80 (1995). In conducting that review, we deem the facts in the complaint to be correct. United States v. Cocoa Berkau, Inc., 990 F.2d 610, 612 (Fed. Cir. 1993). In any event, the facts of this case are not in dispute. The issue before us is one of statutory construction, a question of law that we review de novo. Romero v. United States, 38 F.3d 1204, 1207 (Fed. Cir. 1994).

On appeal, Bristol argues that the district court erred in concluding that the manufacture, use, or sale of Royce's generic version of captopril before February 13, 1996, would not infringe the '776 patent because of the safe harbor provision of the URAA. Bristol contends that the safe harbor provision does not permit infringement by Royce during the Delta period and that, therefore, as mandated by the Hatch-Waxman Act, the effective date of FDA approval of Royce's ANDA may not be earlier than February 13, 1996. For its part, Royce responds that we should affirm, because the district court correctly determined that the URAA permits the manufacture, use, and sale of generic captopril during the Delta period. Accordingly, Royce's paragraph IV certification to the effect that such conduct would not be infringing during the Delta period was correct. Consequently, the certification did not amount to an act of infringement under 35 U.S.C.A. 271(e)(2)(A) so as to entitle Bristol to the remedies of 21 U.S.C. 355(j)(4)(B)(iii) and 35 U.S.C.A. 271(e)(4).

We agree with Bristol. For the reasons set forth below, we hold that the safe harbor provision of the URAA does not permit Royce to make, use, or sell generic captopril during the Delta period. Thus, the statutory bar against FDA approval of Royce's ANDA prior to February 13, 1996 remains in effect. The district court erred in granting Royce's motion to dismiss and in setting aside the bar.

II.

We begin our analysis by considering what the result would be if Royce had filed its paragraph IV certification in the absence of the safe harbor provision of the URAA. This approach brings into sharp focus the question of whether, as the district court held, the safe harbor provision allows Royce to sell its generic version of captopril during the Delta period and therefore makes such sale noninfringing, thereby barring the remedies of the Hatch-Waxman Act that normally would apply.

As seen above, the Hatch-Waxman Act gives a drug patent owner the right to bring an action for infringement upon the filing of a paragraph IV certification. 35 U.S.C.A. 271(e)(2)(A). In that action, depending upon the nature of the certification that has been filed, the district court determines the validity of the patent at issue and/or whether the drug sought to be marketed infringes the claims of that patent. "What is achieved by 271(e)(2) [is] the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing a [paragraph IV] certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." Eli Lilly Co. v. Medtronics, Inc., 496 U.S. 661, 678 (1990). Thus, section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent. If the court deter-

mines that the patent is not invalid and that infringement would occur, and that therefore the ANDA applicant's paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires. See 21 U.S.C. 355(j)(4)(B)(iii)(II); 35 U.S.C.A. 271(e)(4)(A). In addition, the act suspends FDA approval while the infringement suit is pending. See 21 U.S.C. 355(j)(4)(B)(iii).

In this case, it is undisputed that the URAA extended the term of the '776 patent to February 13, 1996. It also is clear that, by amending its ANDA to include a paragraph IV certification, Royce committed an act of infringement under the Hatch-Waxman Act because it sought "to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent." 35 U.S.C.A. 271(e)(2)(A). Finally, it is undisputed that in its paragraph IV certification Royce did not allege either that the '776 patent was invalid or that its generic captopril was not covered by the claims of the patent. See 21 U.S.C. 355(j)(2)(A)(vii)(IV).

Plainly, on these facts, there can be no question that if the district court had not had before it the safe harbor provision of the URAA, it would have been compelled to deny Royce's motion. Since Royce did not challenge the validity of the '776 patent and did not contend that its generic version of captopril was not covered by the claims of the patent, it is clear that if it marketed its product before February 13, 1996, it would be an infringer. Thus, its paragraph IV certification asserting non-infringement during the Delta period would have been incorrect. Under these circumstances, the district court would have had no alternative but to grant Bristol the relief it sought: an order that the effective date of any FDA approval of Royce's ANDA not be earlier

than February 13, 1996. We turn now to the question of whether the URAA changes this outcome.

As noted above, Royce contends that distribution of its generic version of captopril during the Delta period would not constitute infringement of the '776 patent. It bases this contention on the same reasoning that the district court used: the URAA authorizes the sale of products that are covered by the claims of a valid patent. Royce argues that such an "authorized" sale cannot constitute infringement. Put another way, Royce claims that when the URAA says that particular conduct "may continue," it means that the conduct is not infringement. Consequently, Royce asserts, its paragraph IV certification was correct. Therefore, the Hatch-Waxman Act does not bar approval of its ANDA. We reject this reasoning because it is not supported by the language of the statute.

The pertinent portion of the URAA reads as follows: [4]

(2) Remedies. -- The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which --

(A) were commenced or for which substantial investment was made before the date that is six months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of [the extension of the term of the patent].

4 The parties have not pointed to, and we have not discovered, any legislative history on the intent of Congress, at the time of passage of the URAA, regarding the interplay between the URAA and the Hatch-Waxman Act. Therefore, we limit our inquiry to the wording of the statute.

(3) Remuneration. -- The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.

35 U.S.C.A. 154(c).

Contrary to Royce's argument and the holding of the district court, we do not believe that the URAA makes infringing conduct non-infringing during the Delta period. It merely provides that infringing conduct will not give rise to the entire panoply of traditional statutory remedies for patent infringement. Such conduct will give rise only to the limited remedy of equitable remuneration. For us, what compels the conclusion that the URAA does not absolve infringing conduct from being denominated "infringement" during the Delta period is the statutory scheme that the URAA establishes.

By its terms, the URAA applies to "Acts which . . . became infringing" because of the extension of the patent term. The statute then provides that those acts, i.e., acts that became infringing, do not give rise to the remedies of 35 U.S.C. 283, 284, and 285. Such acts may be continued upon the payment of equitable remuneration in an amount determined in an action brought under chapter 28 or chapter 29 of title 35. Chapters 28 and 29 authorize and govern the bringing of actions for infringement. Thus, the design of the URAA is to provide for a patent term extension that renders covered conduct infringing, but then to provide a limited remedy for that kind of infringement, through an action for relief for infringement in the form of equitable remuneration. The statutory scheme does not say, as Royce argues and as the

district court held, "If normally you would infringe, you do not infringe during the Delta period." Rather, it says, "If normally you would infringe, you also infringe during the Delta period. The difference is that, for infringement during the Delta period, you are not subject to the traditional remedies for patent infringement. Instead, you pay the patent owner an equitable remuneration." We are unable to escape the conclusion that if Congress had intended the result urged by Royce -- having the URAA convert infringing conduct into non-infringing conduct during the Delta period -- it would not have established the statutory scheme just described, which points in a different direction. See United States v. International Business Machs. Corp., 892 F.2d 1006, 1009 (Fed. Cir. 1989) ("Had Congress intended to make the exemptions permanent, it knew how: it could and we believe would have used words of futurity.").

The URAA makes no mention of the provisions of the Hatch-Waxman Act. Yet, as the Supreme Court stated in Eli Lilly Co. v. Medtronics, Inc., the Hatch-Waxman Act created "an important new mechanism designed to guard against infringement of patents relating to pioneer drugs," with enforcement provisions that "apply only to drugs and not to other products." 496 U.S. at 676-77. The Act's "mechanism" includes provisions (i) stating that the submission of a paragraph IV certification is "an act of infringement," 35 U.S.C.A. 271(e)(2)(A), and (ii) setting forth the remedies that are available when a patent owner brings an action based upon such "an act of infringement." See 21 U.S.C. 355(j)(4)(B)(iii), 35 U.S.C.A. 271(e)(4). We presume "that Congress is knowledgeable about existing law pertinent to legislation it enacts." VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1581 (Fed. Cir. 1990), cert. denied, 499 U.S. 922 (1991). We believe that if Congress had intended that the URAA affect the Hatch-Waxman Act's finely crafted ANDA approval process in the manner urged by Royce,

at the very least it would have referred to 21 U.S.C. 355(j) and 35 U.S.C.A. 271(e) in the URAA. See United States v. International Business Machs. Corp., 892 F.2d at 1009.

The foregoing analysis is consistent with our recent decision in DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397, 35 USPQ2d 1718 (Fed. Cir. 1995). That case also involved issues arising out of the extension of the term of the '776 patent as a result of the URAA. The appellants in that case were DuPont Merck Pharmaceutical Company, Endo Laboratories, L.L.C., and Mylan Pharmaceuticals Inc. Like Royce, they filed ANDAs seeking FDA approval for the marketing of a generic version of captopril after August 8, 1995. Unlike Royce, however, they chose not to amend their ANDAs to include paragraph IV certifications, as directed by the FDA. Instead, they filed a declaratory judgment action in the United States District Court for the District of Delaware in which, among other things, they sought the following relief: "a declaration that, as long as they pay Bristol-Myers [an] equitable remuneration, they will have authority to make, use, and sell their captopril products after August 8, 1995, and therefore, will not infringe the '776 patent." The district court granted Bristol-Myers's motion to dismiss on the ground that, because the plaintiffs had not filed a paragraph IV certification, no actual controversy existed as required by the Declaratory Judgments Act, 28 U.S.C. 2201 (1988). An appeal to this court followed.

After determining that the district court did in fact have jurisdiction because there was an actual controversy between the parties, we turned to the merits of "the legal relation between section 154(c) of the URAA and the statutory scheme governing FDA approval of ANDAs, see 21 U.S.C. 355(j), 35 U.S.C.A. 271(e)." DuPont Merck Pharmaceutical Co., 62 F.3d at 1401, 35 USPQ2d at 1722. We stated that "[b]ecause this issue is purely legal and

was fully briefed to the district court, in the interests of economy, this court will decide on the merits whether the law entitles DuPont Merck/Endo and Mylan to relief." Id., 35 USPQ2d at 1722. We then stated:

DuPont Merck/Endo and Mylan want to market their generic captopril products before February 13, 1996 -- the date of expiration of Bristol's '776 patent. Thus, should they file amended ANDAs, they will commit infringement under section 271(e)(2).

The only remaining question is whether the URAA converts this otherwise infringing activity during the Delta period to noninfringing activity. Section 154(c) of the URAA exempts qualifying persons who infringe during the Delta period from certain remedies for infringement. Section 154, however, does not authorize infringement. Infringement under section 271(e)(2) before passage of the URAA continues to be infringement after passage of the URAA.

The URAA has no effect, moreover, on the provisions in section 355(j)(4)(B)(iii) triggered by the filing of an infringement suit. Once a patentee files an infringement suit under section 271(e)(2), FDA will suspend its approval of the ANDA. See 21 U.S.C. 355(j)(4)(B)(iii). The patentee may then litigate its infringement suit as aggressively as permitted by law.

In sum, the URAA, by its terms, exempts a qualified infringer from the remedies of sections 283, 284, and 285 of Title 35. The URAA, however, works no change on the definition of infringement under section 271(e)(2) and has no [effect] on the statutory provisions

relating to FDA approval of ANDAs that are triggered by that act of infringement. See 21 U.S.C. 355(j).

Id., 35 USPQ2d at 1722.

We hold that the URAA does not convert Royce's sale of generic captopril during the Delta period into a non-infringing activity. Thus, Royce's paragraph IV certification to the contrary is incorrect. This means that Bristol is entitled to the Hatch-Waxman Act remedy that is "triggered" by the filing of an incorrect paragraph IV certification. That remedy is an order from the district court that the effective date of any approval of Royce's ANDA be not earlier than February 13, 1996, the expiration date of the '776 patent. See 35 U.S.C.A. 271(e)(4)(A). That is precisely the remedy that Bristol sought in the district court. For this reason, the district court should not have dismissed Bristol's suit and should not have set aside the statutory bar against FDA approval of Royce's ANDA. [5]

CONCLUSION

For the foregoing reasons, the district court erred (1) in granting Royce's motion to dismiss Bristol's suit and (2) in setting aside the statutory bar against FDA approval of Royce's ANDA. Accordingly, the judgment in favor of Royce is reversed. The case is remanded to the district court, which is instructed to reinstate both

5 The result would be no different even if, in its paragraph IV certification, Royce had challenged the validity of the '776 patent or had claimed that its product was not covered by the claims of the patent. As we have seen, one of the remedies "triggered" by the filing of a paragraph IV certification is that FDA approval of an ANDA is suspended until any Hatch-Waxman Act infringement suit is resolved. See 21 U.S.C. 355(j)(4)(B)(iii).

Bristol's amended complaint and the statutory bar against FDA approval of Royce's ANDA.

COSTS

Each party shall bear its own costs.

REVERSED and REMANDED with INSTRUCTIONS.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

95-1502

BRISTOL-MYERS SQUIBB COMPANY and E.R. SQUIBB AND SONS, INC.,

Plaintiffs-Appellants,

v.

ROYCE LABORATORIES, INC.,

Defendant-Appellee.

ON MOTION

Before SCHALL, Circuit Judge.

ORDER

Upon consideration of the parties' motion for oral argument,

IT IS ORDERED THAT:

Oral argument shall be heard on October 11, 1995 at 10 a.m.

Date: SEP 15 1995

Alvin A. Schall

Circuit Judge

cc:Robert J. Brookhiser

Milton A. Bass, Esq.

Filed

U.S. Court of Appeals for the Federal Circuit

SEP 15 1995

Francis X. Gindhart

Clerk

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Appeal No. 95-1502

BRISTOL-MYERS SQUIBB COMPANY and E.R. SQUIBB AND SONS, INC.,

Plaintiffs-Appellants,

v.

ROYCE LABORATORIES, INC.,

Defendant-Appellee.

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PLAINTIFFS-APPELLANTS' MOTION TO EXTEND BRIEFING SCHEDULE

Plaintiffs-Appellants Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc. ("Bristol") respectfully move for a short extension of the briefing schedule set in the Court's order of September 1, 1995.

The present schedule allows Bristol only one week from the date of the Order to file its brief, a week that includes a major three-day weekend, and only two days, both weekend days, to prepare and file its reply. Because of the importance of this case and the number of counsel involved, it is respectfully submitted that the schedule is more stringent than can reasonably be accommodated.

Bristol seeks only a short extension of four days, as follows:

Appellant's opening brief -- September 12

Appellee's brief -- September 19

Appellant's reply brief -- September 22

GRANTED

Alvin A. Schall

Filed

U.S. Court of Appeals for the Federal Circuit

SEP -1 1995

Francis X. Gindhart

Clerk

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

95-1502

BRISTOL-MYERS SQUIBB COMPANY

and E.R. SQUIBB AND SONS, INC.,

Plaintiffs-Appellants,

v.

ROYCE LABORATORIES, INC.,

Defendant-Appellee.

ON MOTION

Before SCHALL, Circuit Judge.

ORDER

Royce Laboratories, Inc. moves to expedite this appeal. Royce states that Bristol-Myers Company et al. oppose in part.

Upon consideration thereof,

IT IS ORDERED THAT:

Royce's motion to expedite is granted in part. Bristol's brief is due to be hand-delivered by September 8, 1995; Royce's brief by September 15; and Bristol's reply brief and the Joint Appendix by September 18, 1995. The parties will be informed of the date for oral argument later.

Date: Sep -1 1995

Alvin A. Schall

Circuit Judge

cc: Robert J. Brookhiser, Esq.

Milton A. Bass, Esq.

Filed

U.S. Court of Appeals for the Federal Circuit

SEP -1 1995

Francis X. Gindhart

Clerk

BRISTOL-MYERS SQUIBB CO.
and E.R. SQUIBB & SONS, INC.,

Plaintiffs,

v.

ROYCE LABORATORIES, INC.,

Defendant.

CASE NO. 95-1682-CIV-DAVIS

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA,
MIAMI DIVISION

August 24, 1995, Decided

August 24, 1995, FILED

COUNSEL: For BRISTOL-MYERS SQUIBB COMPANY, E.R. SQUIBB & SONS, INC., plaintiffs: Harley Sheppard Tropin, Kenneth R. Hartmann, Kozyak, Tropin & Throckmorton, Miami, FL.

For ROYCE LABORATORIES, INCORPORATED, defendant: Andrew Cotzin, Broad & Cassel, Miami, FL.

JUDGES: EDWARD B. DAVIS, UNITED STATES DISTRICT JUDGE. MAGISTRATE JUDGE BANDSTRA

OPINIONBY: EDWARD B. DAVIS

OPINION: ORDER ON EMERGENCY MOTION TO SET ASIDE INJUNCTION AND TO DISMISS COMPLAINT

BEFORE THE COURT is Defendant's, Royce Laboratories, Inc.'s ("Royce"), Emergency Motion to Set Aside Injunction and Dismiss Complaint, filed August 11, 1995. [6] [foot note 1 in original] The Court held a scheduling conference on Monday, August 14, at which it ordered an expedited briefing schedule. Having carefully reviewed the Motion, Response and Reply, the Court will grant Defendant's motion to dismiss and grant in part the motion to set aside injunction.

I. BACKGROUND

The facts in this case illustrate an apparent conflict between three related statutes and treaties dealing with patent rights for drug products. In order to resolve

6 [foot note 1 in original] After this motion was filed, Plaintiffs filed an Amended Complaint and Defendant filed a corresponding Emergency Motion asserting the same grounds for dismissal of the amended complaint and dissolution of the injunction.

this conflict, the Court must take a close look at the specific facts presented in light of the overall statutory scheme dealing with the interrelationship between patent status and drug approval.

Plaintiffs, Bristol-Myers Squibb Co. and E.R. Squibb & Sons, Inc. (collectively "Squibb"), own the patent number 4,105,776 (the "'776 patent"), which relates to the heart drug known by the generic name "captopril" and marketed by Squibb under the trademark "Capoten." Patent '776 was scheduled to expire on August 8, 1995. In anticipation of its expiration, Royce made certain investments and commenced a technical research and development plan to obtain United States Food & Drug Administration ("FDA") approval to market and sell a generic form of captopril. On January 3, 1994, Royce formally submitted to the FDA for approval an Abbreviated New Drug Application ("ANDA").[7] **[foot note 2 in original]**

However, on December 8, 1994, President Clinton signed the Uruguay Round Agreement Act ("URAA"), Pub. L. No. 103-465, 108 Stat. 4809 (1994), implementing the United States' participation in the treaty known as the General Agreement of Tariffs and Trade ("GATT"). As part of the URAA, subsection (c) of 35 U.S.C.A. @154 was added to the patent code to extend the expiration dates for certain existing U.S. patents that were in existence and in effect on June 8, 1995, 35 U.S.C.A. @154(c) (West. Supp. 1995). The effect on the '776 patent was to extend its expiration date to February 13, 1996.

7 The FDA announced tentative approval of Royce's ANDA on March 31, 1995. Tentative approval means that the applicant has satisfied all of the scientific and regulatory requirement for final approval. Final approval cannot be forthcoming, however, until the patent status of the drug is resolved. 21 U.S.C.A. @ 355(j)(4)(B)(iii) (1988 & Supp. V 1993).

While drafting the URAA, Congress recognized that extending patent terms could unfairly impact parties who had already made substantial investments based on the expectation of entering the marketplace upon the original expiration of the patent. With this in mind, Congress created a "safe harbor" in section 154(c) to govern the actions of these parties during the transitional period between the original and the extended patent expiration dates, known as the Delta period. See Dupont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co., 1995 U.S. App. LEXIS 21439, App. No. 95-1410 slip op. at 2 (Fed. Cir. Aug. 8, 1995). Hence, Congress envisioned a party entering the marketplace prior to the new expiration date of the patent under the terms and conditions of the "safe harbor." [8] [foot note 3 in original]

The instant lawsuit, though, points out a seemingly insurmountable hurdle blocking entry into the market for drug manufacturers that exists in the form of

8 There is some question whether the "safe harbor" applies to the pharmaceutical industry. This question arises, though, only because it appears that FDA approval provisions conflict with and bar the operation of the "safe harbor" for drug patents. See Department of Health & Human Services Response to Citizen Petition ("HHS Response"), issued May 25, 1995 at 10-12. However, as is discussed below, there is no conflict between these statutes. Drug companies applying for approval can conform to FDA procedure and, at the same time, operate under the safe harbor of the URAA. Hence, there is no reason to exempt drug companies from the "safe harbor" provision of the URAA. See id. at 12 (citing letter from U.S. trade Representative Kantor which indicated that the intention of the language of the provision was to treat all companies equally.)

FDA procedures for approval of new drug applications.[9] [foot note 4 in original] It is the operation of these procedures that are the focus of Plaintiffs' Complaint and Defendant's Emergency Motion.

II. DISCUSSION

In the Complaint, Squibb alleges a single count of patent infringement. However, it does not base its claim on any of the traditional grounds for an infringement suit, but rather alleges a specific, and somewhat artificial, form of infringement created by the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Under section 355(j) of that act a pharmaceutical manufacturer seeking expedited approval to market a generic version of a patented drug may submit to FDA an Abbreviated New Drug Application known as an ANDA. 21 U.S.C.A. @355 (j) (West Supp. 1995). When the patent covering that particular drug has not yet expired, the application must certify either the "date on which [the] patent will expire," (paragraph III certification) or that the patent is "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug for which the [ANDA] is submitted" (paragraph IV certification). 21 U.S.C.A. @ 355(j)(2)(A)(vii)(III), (IV). If the ANDA con-

9 Surprisingly, the Court could find no discussion of thethe potential effect of the URAA on the statutes governing approval of new drug applications, the Hatch-Waxman Act of 1984. See HHS Response at 16.

tains a paragraph IV certification, within 45 days of receiving notice of its filing, a patentee may sue the ANDA applicant claiming the acts will indeed infringe the patent. 21 U.S.C.A. @ 355(j)(4)(B)(iii). If the patentee files suit, the FDA cannot approve the ANDA prior to either the expiration of the patent, judicial resolution of the suit, or 30 months from the patentee's receipt of notice, whichever is earliest. 21 U.S.C.A. @ 355(j)(4)(B)(iii)(I-III).

Following this course, Royce filed an ANDA with a paragraph IV certification [10] [foot note 5 in original] claiming that its manufacture, use or sale of generic captopril during the Delta period will not infringe Squibb's '776 patent because it will be operating under the "safe harbor" created by the URAA. In response, Squibb filed this suit, ostensibly to challenge that claim and to show

10 Royce filed the paragraph IV certification pursuant to an FDA directive issued on May 25, 1995 in response to questions regarding the impact of URAA/GATT on new drug applications. See HHS Response. In that response, the FDA announced the new procedures to be followed for ANDAs pertaining to drugs with extended patent terms. The FDA advised the patent holders to list the extended patent expiration dates with the agency and advised ANDA applicants with pending applications to amend their applications to include a new basis for entry into the market. Id. at 13. Because URAA/GATT extended the patent term for '776 and Squibb listed the new expiration date with the agency, Royce was required to amend its ANDA to include a paragraph IV certification.

that Royce's actions will, indeed, infringe the patent. Hence, the focus of this Court's inquiry is the status of the '776 patent, and whether Royce's paragraph IV certification is correct in claiming that its manufacture, use or sale of generic captopril during the Delta period will not infringe the patent if the FDA approves its ANDA.

Squibb's only challenge to that claim is its argument that Royce infringed its '776 patent when it filed a paragraph IV certification in its ANDA. Squibb's challenge, though, misses the mark. The question for the Court is not whether Royce's application to use the drug infringes the patent, but rather whether its manufacture, use of sale of the drug infringes the '776 patent. Notably, the complaint does not allege such an infringement. Although, Squibb is correct in stating that the act of filing a paragraph IV certification, in and of itself, is an infringing act,[11] [foot note 6 in original] 35 U.S.C.A. @271(e)(2) (1984 & Supp. 1995), this claim of "infringement" alone is insufficient to show that Royce's sale of the drug after FDA approval would infringe the patent.

11 The Court of Appeals for the Federal Circuit, just weeks ago, reaffirmed this finding in specific reference to the interaction between the URAA, and the infringement provisions of the Hatch-Waxman Act. The Court found that "filing such certifications, however, is infringement" and "infringement under section 271(e)(2) before passage of the URAA continues to be infringement after passage of the URAA." Dupont Merck, slip. op. at 8. Put simply, the URAA does not eliminate the procedural protection provided by the Hatch-Waxman Act of having a court determine patent status prior to FDA approval of the ANDA. However, the Federal Circuit did not address the question before this Court, whether filing a paragraph IV certification blocks a drug manufacturer from operating under the "safe harbor" of the URAA.

The key to understanding the dispute between the parties is the difference between the type of infringement created by @271 and the type of infringement that justifies a prohibition on FDA approval of an ANDA. When this difference is made clear, the apparent conflict between the URAA and the provisions of the Hatch-Waxman Act disappears.

The act of infringement created in @271 of the Hatch-Waxman Act was created for a limited and very specific purpose and therefore has a limited and very specific definition. In Eli Lilly, Justice Scalia clarified that the act of infringement created under section 271 "consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678, 110 S. Ct. 2683, 2692, 110 L. Ed. 2d 605 (1990)(emphasis added). The Court emphasized that the purpose of creating this "artificial infringement" was to protect patent holders by providing them an opportunity to resolve any dispute over the status of the patent in the district court prior to FDA approval. Id. at 675-76. It follows that if the paragraph IV certification is subsequently found by the district court to be correct in that the applicant's use of the drug after FDA approval will not infringe the patent, then there is no longer any "artificial infringement" of the patent and the patentee has no actionable claim against the ANDA applicant. See id. at 678-79. Thus, the type of infringement necessary to prohibit FDA approval is an infringing that would occur after FDA approval of the ANDA.

In this case, Royce's paragraph IV certification states that its manufacture, use, or sale of generic captopril, prior to February 13, 1995, will not infringe Squibb's patent because it will be operating under the "safe harbor" created by the URAA. [12] [foot note 7 in original] According to the most recent decision on this issue by the Court of Appeals for the Federal Circuit, Section 154(c) of the URAA

> creates a limited safe harbor for persons who have commenced acts, or made substantial investment toward commission of acts, before June 8, 1995, which become infringing because of the extension of the patent period. Patentees may not assert their traditional patent remedies of 35 U.S.C. @@ 283, 284, and 285 for infringing acts committed by these qualifying persons during the Delta period.

12 Royce claims that it qualifies for the "safe harbor" because it made substantial investments, prior to June 8, 1995, toward the commission of acts which are only infringing because of the extension of the '776 patent. Squibb contests Royce's claimed investments in its response to Royce's emergency motion. Therefore, Squibb states that an evidentiary hearing is necessary to determine this and other issues related to Royce's qualification to operate under the "safe harbor" provision. The Court disagrees. As the term "substantial investment" is not defined in the statute, the Court has little guidance on this issue. The president of Royce, in a sworn statement, indicated that Royce expended $ 1 million in preparing to market captopril, including costs for performing in vivo and in vitro tests and other research necessary to obtain FDA approval of its ANDA. Based on the purpose of Congress in creating the "safe harbor", the Court finds that Royce's expenditures satisfy the investment requirement and qualifies it to operate under the "safe harbor" of URAA.

Dupont Merck slip op. at 2. This "safe harbor" is analogous to similar statutory exceptions created by Congress to permit otherwise infringing acts that are necessary for approval of an ANDA.

The Hatch-Waxman Act created one such exception in section 271(e)(1). In effect, this section allows the otherwise infringing acts of using patented drugs prior to the expiration of the patent if the use is only to develop information necessary to obtain marketing approval. 35 U.S.C.A. @271(e)(1); Eli Lilly, 496 U.S. at 669-672. Section 271(e)(1) states that those acts will not constitute an infringement. 35 U.S.C.A. @ 271(e)(1). Moreover, the Supreme Court in Eli Lilly specifically held that these acts were noninfringing acts. Eli Lilly, 496 U.S. at 679. As a result, patentees have no actionable claim against such users of the patented drug. This exception to permit otherwise infringing activities was created in conjunction with and in exchange for an extension of the existing patent terms. See Eli Lilly, 496 U.S. at 670.

Congress's objective in creating the statutory scheme embodied in the Hatch-Waxman Act was to strike a "careful balance between the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs. This landmark compromise between the interests of the generic drug companies and the pioneer companies was intended to grant a one-time patent term extension in exchange for the prompt availability of generic drug products." HHS Response at 15; Abbreviated New Drug Application Regulations, 59 Fed. Reg. 50338 (1994). Likewise, the URAA affects these same two groups and impacts on the balance achieved between them by the Hatch-Waxman Act. Since Congress recognized this fact,

it is reasonable to believe that it intended not to disturb the delicate compromise when it again extended patent terms under the URAA. Id. ("There is certainly a strong argument to be made that such a compromise should not be upset without hearings and careful deliberation as to the impact [of the URAA] on the twin interests served by the Waxman-Hatch Amendments.").

The only reading of the URAA and the Hatch-Waxman Act that maintains this compromise is that the Act provides the patentees an extended patent term in exchange for allowing the new drug companies to use the patented drugs in an otherwise infringing manner as long as they pay equitable remuneration to the patentees for the commercial use. Under this reading of the governing statutes and treaties, Royce's manufacture, use or sale of the drug within the "safe harbor" of the URAA would not infringe the '776 patent. Thus, its paragraph IV certification stating noninfringement is not in error and no longer constitutes an actionable infringement under section 271. Due to this determination, the Court finds that Squibb's only action against Royce lies in an action for equitable remuneration under the URAA. Since Squibb's complaint does not seek such a remedy, it fails to state a claim upon which relief may be granted.

In this scenario, as in the case where infringement is found, the prohibition against FDA approval has served its purpose of protecting the patentee by having the Court determine the patent status. [13] [foot note 8 in original] But here, since the court determines there would be no infringing activity by Royce after FDA approval, there is no longer a need to prohibit FDA approval of Royce's ANDA. The FDA is free to immediately approve Royce's ANDA. However, Royce may not actually enter the market until it receives a final approval letter from the FDA. [14] [foot note 9 in original]

III. CONCLUSION

In sum, this Court finds that Royce's filing of its amended ANDA containing a paragraph IV certification constituted an act of infringement which triggered the procedures of the Hatch-Waxman Act. The operation of

13 This Court follows the Federal Circuit decision in Dupont Merck in finding that the URAA does not change the definition of 271(e)(2) and has no effect on the statutory provisions relating to FDA approval of ANDA. Dupont Merck, slip. op. at 8. The procedural provisions under @ 271 remain intact, and applicants claiming noninfringement under the URAA must follow these provisions and litigatewhether sale of the drug after FDA approval will infringe the underlying patent.

14 This question of when an ANDA is made effective after judicial resolution of the patent suit was specifically addressed by the FDA. 59 Fed. Reg. 50351 (interpreting the effective date of an ANDA after disposition of the patent litigation to be dependent on final agency approval of the ANDA); 21 C.F.R. @ 314.107(b)(3)(v) ("In order for approval to be made effective under [the] paragraph [dealing with patent litigation], the applicant must receive an approval letter from the agency indicating that the application has received final approval.").

against FDA from approving Royce's drug application until the question of infringement of the '776 patent was resolved by a district court. As this Court finds that Royce's manufacture, use or sale of generic captopril during the Delta period would not infringe the '776 patent pursuant to Section 154 of the URAA, the FDA is no longer enjoined from approving Royce's ANDA, and Plaintiff's complaint for patent infringement fails to state a claim upon which the requested relief may be granted.

Accordingly, it is

ORDERED AND ADJUDGED that Defendant's Motion to Dismiss the Amended Complaint is GRANTED. It is

FURTHER ORDERED AND ADJUDGED that Defendant's Emergency Motion to Set Aside Injunction is GRANTED to the extent that the injunction prohibiting the FDA from approving Royce's ANDA is dissolved. However, the Defendant's request for the Court to order an immediate effective date of its ANDA is DENIED.

DONE and ORDERED in Chambers at Miami, Florida, this 24th day of August, 1995.

EDWARD B. DAVIS

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

BRISTOL-MYERS SQUIBB CO. and E.R. SQUIBB & SONS, INC.,

Plaintiffs,

v.

ROYCE LABORATORIES, INC.,

Defendant.

_____/

Case No. 95-1682-CIV-DAVIS

Magistrate Judge Bandstra

INITIAL SCHEDULING ORDER

THIS CAUSE having come to be heard at a Status/Scheduling Conference held on August 14, 1995, the court having considered the argument of counsel for the parties and being otherwise fully advised in the premises, it is hereby

ORDERED AND ADJUDGED as follows:

1.Plaintiffs' response to defendant, Royce Laboratories' Emergency Motion to Set Aside Injunction and Dismiss Complaint shall be filed (with copies hand-delivered to opposing counsel) on or before August 21, 1995, by 9:30 a.m.

2.Defendant's reply, if any, to plaintiffs' response shall be filed (with copies hand-delivered to opposing counsel) on or before Monday, August 23, 1995, by 9:30 a.m.

DONE AND ORDERED in Chambers at Miami, Dade County, Florida this 15th day of August, 1995.

Edward B. Davis

United States District Judge

Copies furnished to:

Andrew Cotzin, P.A.

Milton A. Bass, Esq.

Harley S. Tropin, Esq.

Robert J. Brookhiser, Esq.

Robert L. Baechtold, Esq.

John D. Kiser, Esq.

Bristol-Myers Squibb Company, Joel M. Lasker, Esq.

35 U.S.C. 154(c):

(c) Continuation.

(1) Determination. The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a), or 17 years from grant, subject to any terminal disclaimers.

(2) Remedies. The remedies of sections 283, 284, and 285 of this title shall not apply to Acts which-- (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act; and

(B) became infringing by reason of paragraph (1).

(3) Remuneration. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this title.".

35 U.S.C. 271(a):

(a) Except as otherwise provided in this title, whoever without authority makes, uses or sells any

patented invention, within the United States during the term of the patent therefor, infringes the patent.

35 U.S.C. 271(e)(2):

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. 271(e)(4):

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. 283:

Injunction

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.

35 U.S.C. 284:

Damages

Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.

When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed.

The court may receive expert testimony as an aid to the determination of damages or of what royalty would be reasonable under the circumstances.

35 U.S.C. 285:

Attorney fees

The court in exceptional cases may award reasonable attorney fees to the prevailing party.

21 U.S.C. 355(j)(2)(A)(vii):

(2) (A) An abbreviated application for a new drug shall contain--

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

21 U.S.C. 355(j)(4)(B)(iii):

(B) The approval of an application submitted under paragraph (2) shall made effective on the last applicable date determined under the following:

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of title 35 or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28 for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

Trips Article 14

Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.

2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.

3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).

4. The provisions of Article 11 in respect of computer programs shall apply mutatis mutandis to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

5 The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, mutatis mutandis, to the rights of performers and producers of phonograms in phonograms.

Trips Article 70

Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, and Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after

the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obligated to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that production in another Member and marketing approval obtained in such other Member.

MOTION FILED
DEC 1 1995

No. 95-737

(2)

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1995

ROYCE LABORATORIES, INC.,
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
AND E.R. SQUIBB & SONS, INC.,
Respondents.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

and

BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS AND GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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14 pp

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MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

This motion for leave to file a brief as amici curiae, and the annexed brief of amici curiae, is respectfully submitted pursuant to Supreme Court Rules 21 and 37, on behalf of the National Association of Pharmaceutical Manufacturers ("NAPM"), and the Generic Pharmaceutical Industry Association ("GPIA") in support of the petition for writ of certiorari filed in the above entitled matter. The annexed brief succinctly presents additional reasons, not set forth in the Petition, why the Writ should be granted in this case.

STATEMENT OF INTEREST OF AMICI CURIAE

NAPM and GPIA are national trade associations, which together for over 40 years have been important advocates for the generic drug industry in the United States. NAPM and GPIA members include manufacturers, distributors, wholesalers, and affiliated companies, who supply the American public with affordable generic pharmaceuticals, and related products. NAPM and GPIA have long played a key role in representing industry viewpoints before the courts, Congress, state legislatures, as well as various federal and state administrative bodies. It is the principal commitment and purpose of NAPM and GPIA to serve industry, consumers, and health care providers by promoting and advancing their shared interest in maintaining a competitive marketplace in which safe and effective drugs are readily available at reasonable prices. Petitioner Royce Laboratories, Inc. ("Royce") is a member of NAPM.

NAPM and GPIA have reviewed the petition for a writ of certiorari filed by Royce and concur in the substance thereof. However, upon such review, NAPM and GPIA believe that certain additional important matters should be called to the Court's attention and for that purpose seek leave to file their proposed amicus curiae brief. The proposed brief succinctly discusses the serious consequences which the decision of the United States Court of Appeals for the Federal Circuit will cause unless review is granted.

It is respectfully submitted that NAPM and GPIA, as the representatives of the generic pharmaceutical industry, should be heard with regard to the petition for a writ of certiorari, which vitally affects the interest of their members. Pursuant to Rule 37 of this Court, counsel for the respondents have been contacted to determine whether they would consent to the proposed filing of the brief. As of the date of filing, Counsel for respondents have not agreed to grant such consent. Petitioner, Royce, has consented to the filing of an amici brief by NAPM and GPIA.

It is respectfully requested that in deciding whether to grant certiorari in this matter vitally affecting the generic pharmaceutical industry, the Court should have the benefit of the additional views of that industry's trade associations. NAPM and GPIA therefore respectfully request that their motion for leave to file the annexed amicus brief be granted.

Respectfully submitted,

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BRIEF OF AMICI CURIAE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS AND GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION, IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

QUESTION PRESENTED

NAPM and GPIA concur in the question presented in the petition for a writ of certiorari. For convenience, that question is set forth below:

> On June 8, 1995, the Uruguay Round Agreements Act ("URAA") took effect, which

inter alia grants a statutory license authorizing non-patentees to make commercial use of products subject to patents whose terms were extended by reason of the URAA. On its face, the statute applies to all such extended patents. The question presented is:

> Did the United States Court of Appeals for the Federal Circuit err when it held that as a matter of law, generic drug manufacturers cannot qualify for the URAA statutory license with regard to pharmaceutical patents whose terms have been extended by URAA?

TABLE OF CONTENTS

Page

QUESTION PRESENTED 4

TABLE OF CONTENTS 5

TABLE OF AUTHORITIES 6

INTEREST OF AMICUS CURIAE 2, 7

REASONS FOR GRANTING THE WRIT 7

CONCLUSION 13

TABLE OF AUTHORITIES

CASES:

Bowen v. Massachusetts,
487 U.S. 879, 896 (1988) 10

Bristol-Myers Squibb et al. v. Royce Laboratories, Inc.,
36 USPQ2d 1641 (Fed. Cir. 1995) 11

STATUTES AND RULES:

35 U.S.C. § 154 9

35 U.S.C. § 154(c) 10

Drug Price Competition and Patent Term
Restoration Act of 1984,
Pub.L. No. 98-417, 98 Stat. 1585 7

Uruguay Round Agreements Act, Pub. L. 103-465,
108 Stat. 4809 (1994) 9

Fed. R. Civ. P. 11 12

Supreme Court Rule 21 2

Supreme Court Rule 37 2

INTEREST OF AMICI CURIAE

The interests of amici curiae NAPM and GPIA is set forth in their motion for leave to file the instant amicus curiae brief. *See* page 2, *infra*. Accordingly it will not be repeated herein.

REASONS FOR GRANTING THE WRIT

THE DECISION OF THE FEDERAL CIRCUIT HAS FRUSTRATED THE CONGRESSIONAL EFFORT TO STRIKE A CAREFUL BALANCE BETWEEN THE INTERESTS OF THE GENERIC AND BRAND-NAME PHARMACEUTICAL INDUSTRIES IN ORDER TO ASSURE THE AMERICAN PUBLIC CAN RECEIVE AFFORDABLE GENERIC VERSIONS OF CRUCIAL DRUG THERAPIES

The Drug Price Competition And Patent Term Restoration Act

The statutory provisions at issue herein were enacted in 1984 as part of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub.L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act"). The prime motivating factor behind that Act was Congress' desire to facilitate the earliest possible availability of affordable generic versions of new drugs. Thus, in exchange for the one-time patent extension benefit conferred upon brand-name drug companies, Hatch-Waxman established the "Abbreviated New Drug Application" procedure by which

generic pharmaceutical companies could obtain approval to market generic versions of existing FDA-approved drugs without having to repeat the basic clinical investigations which had already been performed, and reviewed by FDA, in connection with the full New Drug Application for a particular drug.

Despite its abbreviated nature, however, the ANDA procedure still requires a generic company to conduct extensive bioequivalence and bioavailibilty studies and to submit a detailed application to the FDA. It is not unusual for the entire ANDA process to take several years from inception to final FDA approval. Increasingly, the process requires extensive investments and long-term planning in order to take advantage of marketing opportunities. Artificial delays, -- i.e. those not related to scientific/regulatory requirements -- therefore have a devastating impact on companies which have made marketing plans years in advance only to discover that their substantial capital investments have been frustrated by the inability to obtain an ANDA approval effective on the expected date.

That is the background of the instant case. The Petition for a Writ of Certiorari correctly notes that many ANDAs will be delayed. Even more pertinent is that the substantial capital investments necessary to implement those ANDAs will have been immobilized. The decision of the lower court threatens to prejudice many members of the generic drug industry and their customers during the next several years as a result of (now) misdirected capital applications toward ANDAs which cannot be approved by FDA on a timely basis.

The Uruguay Round Agreements Act

The Uruguay Round Agreements Act, Pub. L. 103-465, 108 Stat. 4809 (1994), enacted pursuant to the General Agreement on Tariffs and Trade, amended numerous provisions of federal law. Most importantly for this case, URAA amended the patent law provisions to alter how patent terms are calculated. For some pharmaceutical patents, this meant a windfall patent term extension.

However, the GATT-URAA patent term revision, 35 U.S.C. § 154, unlike the Hatch-Waxman extension, was *not* granted in order to increase incentives for basic research into new inventions, but rather was merely intended to harmonize U.S. patent law with that of our international trading partners. Thus, when Congress enacted the URAA, it recognized that the patent term revision (from 17 years from grant to 20 years from date of filing) would bestow unearned windfall patent extensions on some current patent holders, at the expense of non-patentees who had begun to prepare for the marketing of generic versions of products at the expiration of the original patent term.

To prevent such an inequitable result, Congress included one of the most important features of the URAA – a transitional statutory license provision. This "grandfather clause" was meant to protect persons who began preparing (prior to the URAA effective date of June 8, 1995) to market a generic version of a patented product on the product's original patent expiration date. It permits them to make use and sell that product *commercially* during the period between the original patent expiration date, and

the later, URAA patent expiration date (the "delta period"), subject only to the payment of "equitable remuneration" to the patent holder. 35 U.S.C. § 154(c). It is this key element of the URAA that the Federal Circuit has now read completely out of the statute with respect to generic pharmaceuticals, although they were a clear and obvious intended beneficiary of the transitional protection.

In response to the URAA's significant change in the patent law, Congress attempted to strike a careful balance between the interests of patent holders and potential competitors who have commenced actions and/or made a substantial investment toward seeking to market patented products. It is well settled that when Congress legislates, it does so with a full awareness and understanding of existing federal law. *See Bowen v. Massachusetts*, 487 U.S. 879, 896 (1988). Thus, when Congress enacted transitional "delta period" protections allowing qualifying non-patentees to market their product between the originally scheduled patent expiration date for a product, and the new URAA-established patent expiration date, Congress must have done so with the awareness that generic pharmaceutical companies would be the obvious intended beneficiaries of that protection.

The lower court's contrary ruling was thus incorrect. If not reviewed, it will have the effect of eviscerating Congressional will by creating an irrational "Catch-22" which denies generic drug companies the ability to exercise their statutory rights under the URAA transitional provisions. The Writ should be granted to review this obstruction to clear federal

law and policy in the area of pharmaceutical patents and drug regulatory approval.

CONGRESS DID NOT INTEND TO INFLICT ENORMOUS EXTRA DRUG COSTS ON THE PUBLIC DURING THE URAA TRANSITION PERIOD

In reaching its decision in this case, the Federal Circuit adopted an illogical and unnecessary interpretation of the URAA which ignores the overriding purpose of Congress in both the URAA and the Hatch-Waxman Act. That Congressional purpose was to foster and encourage the earliest possible availability of generic drugs to the American public. Utterly ignoring that Congressional imperative, the Federal Circuit went out of its way to conjure an interpretation of the URAA that attributes to Congress -- contrary to the provisions of the URAA itself -- an intention to abandon its long-held national policy goal on the basis that Congress did not expressly re-state and reaffirm that goal when enacting the URAA. Thus the panel decision noted that it could not locate any legislative history to the URAA regarding the interplay between the URAA and Hatch-Waxman Act, and purported to "limit our inquiry to the wording of the statute." *Bristol-Myers Squibb et al. v. Royce Laboratories, Inc.*, 36 USPQ2d 1641, 1646, n.4 (Fed. Cir. 1995).

In its reading of the statute, which was characterized at oral argument by one of the panel members as a "muddle," the panel reached a result which totally undermines both the Congressional intent of the Hatch-Waxman Act and the protective provisions of the URAA. Thus the lower court, based

on a lack of legislative history, discerned in the statutory muddle a Congressional intent to abandon the decade-old national priority of timely public access to affordable generic versions of life-saving pharmaceutical products, despite the presence in URAA of a provision uniquely designed to preserve that priority as to affected products. Presumably, the same lack of legislative history will not bar generic manufacturers of even the most inconsequential non-pharmaceutical products from marketing their product during the delta period. The lower court's creation of an unwritten statutory prohibition against delta period sales of ANDA-drug products cannot be allowed to stand because it jettisons Congress's, and the public's vested interest and expectation in the availability of lower cost generic drug alternatives beginning on the originally-scheduled patent expiration date.

The generic drug industry can ill afford expensive and time consuming legal battles with the brand name drug companies over the issues of implementing the URAA provisions. Moreover, because of its exclusive jurisdiction in patent matters, the decision of the Federal Circuit has laid down the law which FDA and the generic drug companies are saddled with unless this court intervenes. Indeed, contrary to the argument of Respondents Bristol-Myers Squibb Co. and E.R. Squibb & Sons, Inc., in opposition to Royce's motion to expedite consideration of its petition for certiorari, the emphatic and jurisdictionally-exclusive ruling of the Federal Circuit, in light of the requirements of Fed. R. Civ. P. 11, will mean that as a practical matter, the present case will be the only opportunity for this court to address these issues.

The outcome of this case will affect billions of dollars of either consumer cost or consumer savings, but only for one industry -- the generic pharmaceutical industry. The decision of the Federal Circuit is wrong because it because it defies common sense. It should be reversed by this court at the earliest opportunity.

CONCLUSION

For the reasons stated herein, and for the reasons stated in the Petition for Writ of Certiorari, amici curiae NAPM and GPIA respectfully urge the Court to issue the Writ and to expedite the resolution on the merits of this vitally important issue.

Respectfully submitted,

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BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417) ("Hatch-Waxman Act") governs the filing and approval of abbreviated new drug applications ("ANDAs") to market generic versions of previously approved new drugs and provides that it is an act of infringement to file an ANDA seeking approval by the Food and Drug Administration to market a generic drug product prior to the expiration of any patent which covers that drug. 35 U.S.C. § 271(e)(2). The exclusive remedies for such acts of infringement are provided in 35 U.S.C. § 271(e)(4), including an order that the "effective date of any [FDA] approval of the drug . . . [shall] be a date which is not earlier than the date of the expiration of the patent that has been infringed." 35 U.S.C. § 271(e)(4)(A).

The Uruguay Round Agreements Act ("URAA"), Pub. L. No. 103-465, 108 Stat. 4809 (codified in part at 35 U.S.C. § 154(c) (West Supp. 1995), enacted December 8, 1994, 21 U.S.C. § 154(c)(2), (3)), redefined the terms of various patents and limited certain remedies available to patentees. The transition provision of the URAA states:

> (2) REMEDIES. The remedies of sections 283, 284, and 285 of this title [35 U.S.C.A.] shall not apply to Acts which --
>
> (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act [June 8, 1995]; and
>
> (B) became infringing by reason of paragraph (1) [the redefined expiration date].

> (3) REMUNERATION. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2) of this title [35 U.S.C.].

The questions presented by the Petition are:

1. Does the transition provision of the URAA, which refers only to the remedies of 35 U.S.C. §§ 283, 284 and 285, abrogate the remedy provided by 35 U.S.C. § 271(e)(4)(A) for an act of infringement under 35 U.S.C. § 271(e)(2)?

2. Does the transition provision of the URAA render certain acts committed during the transition period non-infringing, or only limit certain remedies that are available to the patentee for acts that are infringing?

PARTIES TO THE PROCEEDING

The names of all parties in the court whose judgment is sought to be reviewed appear in the caption of this Brief in Opposition.

LIST OF PARTIES PURSUANT TO RULE 29.6

Bristol-Myers Squibb Company has no parent corporation. E.R. Squibb & Sons, Inc. is a wholly-owned subsidiary of Bristol-Myers Squibb. Set forth below is a list of non-wholly owned subsidiaries of Bristol-Myers Squibb Company.

Bristol-Myers Lion Ltd. (Japan)
Bristol-Myers S.A. (France)
Bristol-Myers Squibb G.m.b.h. (Germany)
Bristol-Myers Squibb Korea Limited (Korea)
Mead Johnson (Guangzhou) Ltd. (China)
P.T. Squibb Indonesia (Indonesia)
Squibb of Bangladesh Limited (Pakistan)
Synbiotics Limited (India)
Instituto Bio-Medico S.A. de C.V. (Mexico)
Laboratories UPSA SAS (France)
Myagen (France)
RCS Realty Corporation (Philippines)
Servicios Bio-Medicos de Compresion S.A. (Mexico)
Sino American Shanghai Squibb Pharma Ltd. (China)
SMI Bristol Limited (Japan)
Squibb Nigeria Limited (Nigeria)
UPSA Investissements (France)
2309 Realty Corporation (Philippines)

TABLE OF CONTENTS

QUESTIONS PRESENTED i

PARTIES TO THE PROCEEDING iii

LIST OF PARTIES PURSUANT TO RULE 29.6 iii

TABLE OF AUTHORITIES vi

OPINIONS BELOW 2

JURISDICTION 2

COUNTERSTATEMENT OF THE CASE 2

A. The Statutory Framework 3

1. The Hatch-Waxman Act 3

2. The URAA 5

3. FDA Policy Decision 6

B. The Captopril Patent 8

C. The DuPont-Merck Case 8

D. The Dispute Between the Parties 9

1. Royce's ANDA 9

2. The District Court Proceedings 10

3. The Decision Below 12

REASONS FOR DENYING CERTIORARI 14

I. THE DECISION BELOW IS CORRECT AND DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR ANY COURT OF APPEALS 14

A. There Is No Conflict with Any Decision of This Court 14

B. The Decision Below Does Not Conflict with Any Other Court of Appeals Decisions 15

C. The Decision Below Correctly Applies the Plain Language of the Statute 16

II. THE PETITION DOES NOT PRESENT AN ISSUE OF GENERAL PUBLIC IMPORTANCE 20

CONCLUSION 23

APPENDIX: FDA RESPONSE TO GLAXO'S CITIZEN PETITION App.-1

TABLE OF AUTHORITIES

CASES

Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc. v. Royce Laboratories, Inc., 36 U.S.P.Q. 2d 1641 (Fed. Cir. 1995).....*passim*

Burlington Northern R.R. v. Oklahoma Tax Commission, 481 U.S. 454 (1987).....22

Connecticut National Bank v. Germain, 503 U.S. 249 (1992).....22

DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co., 62 F.3d 1397 (Fed Cir. 1995).....2,3,8,9,16

Eli Lilly Co. v. Medtronics, Inc., 496 U.S. 661 (1990).....12,14,15

Laing v. United States, 423 U.S. 161 (1976).....21

Layne & Bowler v. Western Well Works, Inc., 261 U.S. 387 (1923).....15

Morton v. Ruiz, 415 U.S. 199 (1974).....16

STATUTES

21 U.S.C. § 355(j)(1994).....3,9,13,20

21 U.S.C. § 355 (j)(2)(A)(vii)(III).....4

21 U.S.C. § 355 (j)(2)(A)(vii)(IV).....4

21 U.S.C. § 355 (j)(2)(B).....10

21 U.S.C. § 355 (j)(2)(B)(i).....4

21 U.S.C. § 355 (j)(4)(B)(iii).....4

28 U.S.C. § 1254(1)(1988).....2

28 U.S.C. § 1338(a)(1988).....2

The Uruguay Round Agreements Act (URAA),
Pub. L. No. 103-465, 108 Stat. 4809
(codified in part at 35 U.S.C.A. § 154(c)
(West Supp. 1995), enacted Dec. 8, 1994).....5,6

35 U.S.C. § 154(c).....13,17

35 U.S.C. § 154(c)(2).....22

35 U.S.C. § 154(c)(2)(B).....17

35 U.S.C. § 271(e).....13,19,20

35 U.S.C. § 271(e)(1).....4,14,17,19

35 U.S.C. § 271(e)(2).....4,7,10,11,13,15,16,17,19

35 U.S.C. § 271(e)(2)(A).....10,12

35 U.S.C. § 271(e)(4).....4,7,10,13,17, 19

35 U.S.C. § 271(e)(4)(A).....4,10,13,17,19

35 U.S.C. § 271(g).....19

35 U.S.C. § 283.....5,7,13,17,19

35 U.S.C. § 284.....5,7,13,17,19

35 U.S.C. § 285.....5,7,13,17,19

35 U.S.C. § 287(a) 19

35 U.S.C. § 287(b)(2) 19

42 U.S.C. § 2183(b)(2)(1988) 17

42 U.S.C. § 7608 (1988) 17

OTHER AUTHORITIES

21 C.F.R. § 314.307(e)(1995) 12

54 Fed. Reg. 28,872, 28,894 (July 10, 1989) 12

57 Fed. Reg. 50,338, 50,353 (Oct. 3, 1994) 12

141 Cong. Rec. S6495 (daily ed. May 11, 1995) 21

141 Cong. Rec. S12388-12391 (August 11, 1995) 21

Chemical Marketing Reporter (January 2, 1995) 21

H. R. Doc. No. 316, 103d Cong., 2d Sess. 1003 (1994) 22

No. 95-737

IN THE
Supreme Court Of The United States
October Term, 1995

ROYCE LABORATORIES, INC.
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY,
AND E.R. SQUIBB & SONS, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court Of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

Bristol-Myers Squibb Company and E.R. Squibb & Sons, Inc. (collectively "Bristol") file this brief in Opposition to the Petition for a Writ of Certiorari filed by Petitioner, Royce Laboratories, Inc. ("Royce").

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 36 U.S.P.Q. 2d 1641 (Fed. Cir. 1995) and is reproduced in the Appendix to the petition, beginning at page A-1. The opinion of the district court is reported at 36 U.S.P.Q. 2d (BNA) 1637 (S.D.Fla. 1995) and is reproduced, along with the district court order, in the Appendix to the petition, beginning at page A-27.

JURISDICTION

The judgment of the Court of Appeals was entered on November 1, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1) (1988). The jurisdiction of the district court rested on 28 U.S.C. § 1338(a) (1988).

COUNTERSTATEMENT OF THE CASE

The dispute between the parties concerns Royce's attempt to obtain approval by the Food and Drug Administration ("FDA") to market a generic version of a patented prescription pharmaceutical product (captopril) made by Bristol *prior* to the expiration date of Bristol's patent covering that product. Royce did so by amending its abbreviated new drug application ("ANDA") with the FDA to contain a certification that Bristol's patent was invalid or unenforceable. Under the Hatch-Waxman Act, this is an act of patent infringement.

There is no dispute that Bristol's patent is valid and that it covers Royce's generic drug product. Royce's only "defense" to its admitted act of infringement is the claim that the recently enacted Uruguay Round Agreements Act ("URAA") provides it with a "statutory license" to market captopril prior to expiration of Bristol's patent. A panel of the Federal Circuit held that the URAA did not do so. A

different panel of the Federal Circuit had previously reached the same conclusion in another case involving Bristol's captopril patent brought by two other generic drug companies. *See DuPont Merck Pharmaceutical Co. v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed Cir. 1995). Neither of the plaintiffs in that case sought review by this Court.

The decisions by these two different panels of the Federal Circuit are consistent with an FDA policy decision issued May 25, 1995. There has been no judicial challenge to the FDA policy.

A. The Statutory Framework

The legal issue decided below concerns the relationship between the provisions of the URAA and the Hatch-Waxman Act.

1. The Hatch-Waxman Act

The Hatch-Waxman Act introduced provisions to both the Patent Code and the Food Drug and Cosmetic Act to govern the filing, approval and effective date of approval of ANDAs which seek approval by FDA to market generic versions of previously approved new ("pioneer") drugs.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer seeking approval to market a generic version of a patented drug may submit to FDA an abbreviated new drug application (ANDA).[1] 21 U.S.C. § 355(j) (1994). As part of the ANDA process, when the patent has not expired, the generic drug manufacturer must certify either the "date on which [the] patent will expire" (a paragraph III

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[1] An ANDA permits a generic manufacturer to rely on the data that research-based companies generated at great time and expense to develop and secure original FDA approval of the drug.

certification) or that the patent is "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug for which the [ANDA] is submitted" (a paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii)(III), (IV).

If an ANDA contains a paragraph IV certification, the ANDA applicant must give notice to the patentee and must provide detailed bases for its belief that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B)(i). The patentee then has 45 days to sue the ANDA applicant for infringement. 21 U.S.C. § 355(j)(4)(B)(iii). If the patentee files suit within that period, then FDA approval does not occur until expiration of the patent, judicial resolution of the infringement suit, or thirty months from the patentee's receipt of notice, whichever is earliest. *Id.*

The Hatch-Waxman Act also added provisions to the Patent Code that relate specifically to the generic drug approval process. Section 271(e)(2) states that it shall be an act of infringement to submit an ANDA "if the purpose of such submission is to obtain approval under [the FD&C Act] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."[2] 35 U.S.C. § 271(e)(2). Section 271(e)(4) lists the remedies available for infringement under section 271(e)(2), and states that these are the "only remedies" for such an act of infringement. One of these remedies is an order that the "effective date of any [FDA] approval of the drug . . . be a date which is not earlier than the date of the expiration of the patent that has been infringed." 35 U.S.C. § 271(e)(4)(A). The remedy of section 271(e)(4)(A) is specifically identified as one of the remedies which a court may order in an action by the patentee in response to a paragraph IV certification. *See* 21 U.S.C. § 355(j)(4)(B)(iii).

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2 Section 271(e)(1) establishes that it is not an act of infringement to use a patented drug solely for purposes related to obtaining regulatory approval of the product. 35 U.S.C. § 271(e)(1).

2. The URAA

The URAA was enacted in December 1994 to implement the Uruguay Round Agreements, a series of multilateral trade agreements, which includes the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).

URAA's provisions amend Title 35 of the U.S. Code to redefine the period of patent protection for some patents. Section 532(a)(1) of the URAA provides, *inter alia*, that, for patents in force on June 8, 1995, or that result from an application filed before that date, the patent term shall be the greater of 17 years from the granting of the patent or 20 years from the date on which the application for the patent was filed, or under certain circumstances 20 years from the date of the earliest patent application filing.

The URAA contains a transitional provision governing acts that will become infringing due to the extension of patents in effect or already filed as of June 8, 1995. While both Royce and *amici* characterize this provision as a "statutory license," section 532(a)(1) of the URAA merely limits the availability of certain specific statutory patent infringement remedies for acts that were commenced, or for which substantial investment was made, before June 8, 1995, and which become infringing because of the extension of the patent period.

Thus, section 532(a)(1) provides that the remedies set out in sections 283, 284, and 285 of Title 35 (which provide for injunctions, damages, and attorney and fees) will not apply to infringing acts during this period.[3] In lieu of those

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3 Section 532 of the URAA provides:

> (c) CONTINUATION . . .
>
> (2) REMEDIES. The remedies of sections 283, 284, and 285 of this title [35 U.S.C.] shall not apply to Acts which --

remedies, the statute provides for payment of "equitable remuneration." The transition provision of URAA does not refer to or limit the remedies set out in section 271(e)(4).[4] The Hatch-Waxman Act provides that these are the "only remedies" available for the act of infringement at issue in this case, *i.e.*, infringement under section 271(e)(2). 35 U.S.C. § 271(e)(4).

3. FDA Policy Decision

The effect of URAA's redefined patent terms on the ANDA process was the subject of a notice and comment proceeding conducted by the FDA in which representatives of all segments of the pharmaceutical industry, including

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> (A) were commenced or for which substantial investment was made before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act [June 8, 1995]; and
>
> (B) became infringing by reason of paragraph (1) [the redefined expiration date].
>
> (3) REMUNERATION. The acts referred to in paragraph (2) may be continued only upon the payment of an equitable remuneration to the patentee that is determined in an action brought under chapter 28 and chapter 29 (other than those provisions excluded by paragraph (2)) of this tile [35 U.S.C.A.].
>
> URAA, Pub. L. No. 103-465, 108 Stat. 4809, 4984-85 (codified at 35 U.S.C.A. § 154(c)(West Supp. 1995)).

[4] Congress was clearly aware of these provisions when enacted the URAA since, as the FDA has recognized, they are amended by other provisions of the URAA, albeit in ways not relevant here. *See* App.-14. In this regard, the URAA provides that: "Nothing in this Act shall be construed . . . to amend or modify any law of the United States, including any law relating to--(I) the protection of human, animal or plant life or health, . . . unless specifically provided for in this Act." Section 102(a)(2).

both generic and pioneer companies, submitted comments. In a May 1995 letter, the FDA issued its decision on this issue, concluding that the URAA provisions do not affect acts of infringement under 35 U.S.C. § 271(e)(2) or the remedies for that act of infringement under 35 U.S.C. § 271(e)(4). *See* Appendix ("App.").

Despite its expressed desire to do so, the FDA "[could] not find a basis for adopting the interpretation of the URAA that 35 U.S.C. 154, as amended, applies to infringements through ANDA submissions, which are governed by 35 U.S.C. 271(e)." App. 13-14. The FDA recognized that "the URAA is not 'silent or ambiguous' on the question of applying the transitional provision to the generic drug approval process." App. 13. Applying the "plain language" of the transitional provision of the URAA, FDA concluded that this provision simply "limits the remedies available to a patentee in a suit brought against an infringer whose actions became infringing due to the URAA patent extension." App. 14. In support of its conclusion, the FDA observed that the URAA's transition provision specifically lists the three remedial provisions that are unavailable, *i.e.*, 35 U.S.C. 283, 284, and 285, but "does not list among the unavailable remedies section 271(e)(4), which provides for injunctions, damages, and attorney fees for infringement actions arising from a manufacturer seeking approval from FDA to market a generic version of a patented drug product before the patent on the product expires." App. 14. Responding to arguments by generic pharmaceutical manufacturers that this was an inadvertent legislative oversight, the FDA noted that this "is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence," since the URAA made other amendments to section 271(e)(4). App. 14.

Respondents are aware of no court challenge to the FDA policy decision.

B. The Captopril Patent

Bristol owns United States Patent 4,105,776 (the "captopril patent"), which discloses and claims the chemical compound having the generic name "captopril." Captopril was developed, and marketed by Bristol under the trademark Capoten®, for the treatment of hypertension, heart failure, diabetic nephropathy, and left ventricular dysfunction following myocardial infarction. The compound is the first marketed compound in a class of drugs known as angiotensin converting enzyme ("ACE") inhibitors. When it issued on August 8, 1978, the expiration date of the captopril patent was August 8, 1995. Under the URAA, the expiration date of United States Patent 4,105,776 is now February 13, 1996.

C. The DuPont-Merck Case

The instant case was preceded by another court proceeding involving Bristol's captopril patent. *DuPont Merck v. Bristol-Myers Squibb Co.*, 62 F.3d 1397 (Fed. Cir. 1995). Two generic drug manufacturers sued Bristol, contending that the URAA transition provision gave them a "license" or "authority" to market captopril prior to the redefined term of the captopril patent if they paid "equitable remuneration" to Bristol.

The district court dismissed plaintiffs' declaratory judgment action for lack of jurisdiction, holding that there was no "actual case or controversy" because the two generic manufacturers had not amended their ANDAs to include paragraph IV certifications challenging the validity, infringement or enforceability of Bristol's captopril patent.

On appeal, the Federal Circuit found that there was jurisdiction. Rather than remand, however, the court of appeals proceeded to resolve "the merits of the dispute," holding that the generic companies have not stated a claim "upon which relief may be granted" and "are not entitled to

relief as a matter of law." 62 F.3d at 1402. Applying the plain language of the URAA, the court of appeals held:

> In sum, the URAA, by its terms, exempts a qualified infringer from the remedies of sections 283, 284, and 285 of Title 35. The URAA, however, works no change on the definition of infringement under section 271(e)(2) and has no affect on the statutory provisions relating to FDA approval of ANDAs that are triggered by that act of infringement. *See* 21 U.S.C. § 355(j).

Id. A petition for rehearing was denied on August 28, 1995. Plaintiffs did not seek review by this Court.

D. The Dispute Between the Parties

1. Royce's ANDA

Royce filed an ANDA seeking approval to market a generic version of captopril. As originally filed, Royce's application contained a paragraph III certification stating that the captopril patent expired on August 8, 1995. After the enactment of URAA, that certification was no longer accurate, and FDA could not lawfully approve Royce's ANDA. Consequently, Royce amended its ANDA by eliminating the paragraph III patent certification and substituting a paragraph IV certification.

As required by the Hatch-Waxman Act, Royce notified Bristol of the paragraph IV certification. Royce did not (and does not) contend that the captopril patent was invalid or that the claims of the patent did not cover Royce's generic captopril product. The sole basis of Royce's "opinion" that the patent will not be infringed is its

contention that the transition provision of the URAA gives Royce a "statutory license" to market captopril during the period August 8, 1995 to February 13, 1996 because Royce had made a "substantial investment" in anticipation of marketing captopril and Royce will pay Bristol "equitable remuneration."

2. The District Court Proceedings

Bristol filed suit against Royce in the United States District Court for the Southern District of Florida, alleging that Royce had infringed Bristol's captopril patent in violation of 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA seeking FDA approval to market a generic version of captopril before the expiration of Bristol's patent. Bristol alleged that Royce's paragraph IV certification was "insufficient and inadequate on its face, and inconsistent with applicable law."

Bristol sought judgment that (i) the captopril patent is valid and has been infringed by Royce and (ii) the court enter an order pursuant to 35 U.S.C.A. § 271(e)(4)(A) that the effective date of any FDA approval of Royce's ANDA under 21 U.S.C. § 355(j)(4)(B) be a date not earlier than the February 13, 1996 expiration date of the captopril patent.

One week after the complaint was filed, Royce filed an emergency motion "To Set Aside The Injunction Delaying The Food And Drug Administration's Approval Of Defendant's Abbreviated New Drug Application And To Dismiss The Complaint." In support of its motion, Royce reiterated the contentions contained in its paragraph IV notice to Bristol, and submitted a declaration of its president, averring that Royce had spent over $1 million in connection with the preparation and filing of its ANDA.

Bristol opposed Royce's motion to dismiss on two grounds. *First*, as a matter of law, the URAA does not abrogate the remedies of section 271(e)(4) that result from a section 271(e)(2) act of infringement. *Second*, even if the

URAA provides a "statutory license" of the sort claimed by Royce, there was no way to ascertain whether Royce satisfied the factual predicate of a "substantial investment" on a motion to dismiss because it required discovery and an evidentiary hearing.

On August 24, 1995 (without permitting any discovery on the factual issues in dispute), the district court issued an order granting Royce's motion to dismiss and dissolving the statutory stay on FDA approving Royce's ANDA.[5] Although the district court found that Royce had committed the act of infringement under 35 U.S.C. § 271(e)(2) alleged in the complaint (*i.e.*, filing an ANDA seeking FDA approval to market a generic drug product prior to the expiration of the captopril patent), it held that this act of infringement was not actionable because the "safe harbor" provision of URAA made the ultimate commercial manufacture and marketing of captopril non-infringing.[6]

Bristol appealed.

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[5] However, the District Court refused to order the FDA to make approval of Royce's ANDA immediately effective. A-39.

[6] On the basis of the untested, conclusory assertion in an affidavit submitted by Royce in support of its motion to dismiss, the district court then found that Royce satisfied the URAA requirement of "substantial investment" made prior to June 8, 1995. A-37. Although it recognized that Bristol contested the factual and legal adequacy of Royce's claimed investment and sought discovery and an evidentiary hearing on this issue, the district court (in a footnote) concluded that Royce had, in fact, made a $1 million investment, and that, as a matter of law, this constituted a "substantial investment" within the meaning of the URAA. *Id.* The district court ruled that Bristol therefore had no cause of action other than a claim for "equitable remuneration." *Id.*

3. The Decision Below

The Federal Circuit reversed the decision of the district court.[7]

The court of appeals first examined the application of the Hatch-Waxman Act requirements to Royce's ANDA in the absence of the URAA. Applying this Court's decision in *Eli Lilly Co. v. Medtronics, Inc.*, 496 U.S. 661 (1990), the court of appeals stated that, in an action for patent infringement under section 271(e)(2)(A), the court must "determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." A-12 (emphasis in original). The court recognized that if "the patent is not invalid and the infringement would occur," the ANDA applicant's paragraph IV certification is incorrect and the patentee is entitled to an order that FDA approval of the ANDA cannot be made effective prior to expiration of the patent. Since Royce did not allege that the captopril patent is invalid or that its claims did not cover Royce's generic captopril product, the court of appeals found that (in the absence of the URAA), Royce would infringe Bristol's patent if it marketed captopril prior to the February 13, 1996 expiration date of the patent. A-13.

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[7] While Bristol's Federal Circuit appeal was pending, Royce filed a petition with the United States Court of Appeals for the Eleventh Circuit, challenging the validity of an FDA regulation, 21 C.F.R. § 314.307(e)(1995), which provides that FDA approval of an ANDA which challenges the validity, enforceability of infringement of a patent will be made effective on the date of an appellate decision that the patent is invalid, unenforceable or not infringed. The reasons for this Rule were set out at length in Federal Register notices proposing and adopting the regulation. *See* 54 Fed. Reg. 28,872, 28,894-95 (July 10, 1989); 57 Fed. Reg. 50,338, 50,353 (Oct. 3, 1994). Relying on the decision of the district court in this case, Royce asked the Eleventh Circuit to order the FDA to make its ANDA effective immediately -- relief that the district court had refused to provide. Following the decision of the Federal Circuit, Royce's petition was dismissed as moot on December 2, 1995.

The court then proceeded to determine whether the URAA altered this conclusion. Examining the language of the URAA transition provision, 35 U.S.C. § 154(c), the court found that the URAA does not make "infringing conduct non-infringing during the Delta period." A-15. After noting that the plain language of the URAA merely limits remedies for certain types of infringing conduct, *i.e.*, the remedies of 35 U.S.C.A. §§ 283, 284 and 285, the court recognized that "the URAA makes no mention of the provisions of the Hatch-Waxman Act," including the provisions for acts of infringement under section 271(e)(2) and the remedies that are available to the patentee under 35 U.S.C. section 271(e)(4) based on that act of infringement. As did the FDA before it, the court pointed out that, if Congress had intended to alter the Hatch-Waxman Act's "finely crafted ANDA approval process, in the manner urged by Royce, at the very least it would have referred to 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e). . . ." A-16-17.

Accordingly, the court held that the URAA "does not convert Royce's sale of generic captopril during the Delta period into a non-infringing activity." A-19. As a result, Royce's paragraph IV certification to the contrary was incorrect, entitling Bristol to the remedy of section 271(e)(4)(A).

The court did not reach the alternate ground for reversal urged by Bristol based on the district court's improper resolution of factual issues on Royce's motion to dismiss..

After filing its Petition for Writ of Certiorari (and a motion for expedited consideration) in this Court, Royce filed a petition for rehearing with the Federal Circuit. On December 8, 1995, the petition for rehearing was denied.

REASONS FOR DENYING CERTIORARI

The petition should be denied because the decision of the Court of Appeals below is correct, does not conflict with

any decision of this Court or any other court of appeals and does not present an important question for resolution by this Court.

I. THE DECISION BELOW IS CORRECT AND DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT OR ANY COURT OF APPEALS

The court of appeals carefully considered and rejected the arguments raised here by petitioner. There is no conflict between the decision below and the decision of any other court of appeals or this Court. To the contrary, this was the *second* time that a panel of the Federal Circuit reached the same conclusion in a case with respect to Bristol's captopril patent. The decision below was correct and fully in accordance with applicable Supreme Court precedent, the plain meaning of the statutes involved and the policy of the FDA, *viz.* the federal agency with specific statutory responsibility for administering the Hatch-Waxman Act.

A. There Is No Conflict with Any Decision of This Court

The Petition contends that the decision below conflicts with the decision of this Court in *Eli Lilly Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990). Pet. at 25. That is not so.

In the first place, the *Eli Lilly* case did not address the interrelationship between the URAA and the Hatch-Waxman Act which was the subject of the decision below. Rather, *Eli Lilly* dealt with the issue of whether certain of the patent provisions of the Hatch-Waxman Act (35 U.S.C. § 271(e)(1)) applied to medical devices.

Moreover, the decision below is completely in accord with this Court's decision in *Eli Lilly*. The lower court

specifically cited *Eli Lilly* and applied the method for evaluating the act of patent infringement under 35 U.S.C. § 271(e)(2) that is set out in the Court's opinion in *Eli Lilly*. Contrary to the suggestion of the Petition, the lower court did *not* conclude that the mere filing of a paragraph IV certification entitled Bristol to the relief it sought. Rather, the lower court looked to see whether the ANDA applicant's paragraph IV certification was correct, *i.e.*, whether the patent at issue is valid and, if so, whether sale of the generic product at issue infringed that patent. This was the very analysis that Royce asked the court to apply on the basis of *Eli Lilly*. A-11.

Furthermore, the lower court properly recognized that if, in enacting the URAA, Congress had meant to alter the delicate balance of provisions in the Hatch-Waxman Act, as described by this Court in *Eli Lilly*, it would have done so explicitly and not by implication, as Royce suggests. App. - 16-17. The lower court cited *Eli Lilly* for the indisputable proposition that the provisions of the Hatch-Waxman Act created "an important new mechanism designed to guard against infringement of patents relating to pioneer drugs" with enforcement provisions that "apply only to drugs and not to other products." 496 U.S. at 676-79. App. - 16.

In short, there is no conflict whatsoever between the decision below and this Court's decision in *Eli Lilly*, and certainly no irreconcilable "conflict" of the sort that might support review by this Court. *See, e.g., Layne & Bowler v. Western Well Works, Inc.*, 261 U.S. 387, 393 (1923).

B. The Decision Below Does Not Conflict with Any Other Court of Appeals Decisions

Although Royce suggests that the issues raised in the petition are novel, they have been previously considered in several different forums, with consistent results. As a result,

review by this court is not necessary to reconcile conflicting appellate or administrative decisions.

The decision of the lower court is the second decision by a panel of the Federal Circuit which has rejected the contention that the URAA grants a "license" to generic drug manufacturers to market captopril prior to the expiration of Bristol's admittedly valid patent. Thus, in *DuPont Merck* (cited in the decision below), a *different* panel of the Federal Circuit rejected the claims of two other generic drug companies that the URAA gave them a right to market captopril before expiration of the captopril patent, as redefined by the URAA. Far from a conflict, there is complete accord between the only two pertinent appellate decisions on this issue.

Nor does the decision below conflict with any administrative policy or interpretation of the Food and Drug Administration -- the administrative agency with statutory responsibility for implementing the ANDA process established by the Hatch-Waxman Act. To the contrary, the FDA specifically concluded that the URAA does not affect the remedies available for acts of infringement under section 271(e)(2). That is also what the lower court found. There has been no court challenge to FDA's policy, and there is no conflict between that policy and the decision below. *Compare Morton v. Ruiz*, 415 U.S. 199, 201-02 (1974) (decision below asserted to be "inconsistent with long-established policy of the Secretary [of the Interior] and of the Bureau").

C. The Decision Below Correctly Applies the Plain Language of the Statute

In an effort to secure review by this Court, both Royce and *amici* ignore the actual language used by Congress in enacting the URAA and misstate the decision of the lower court.

First, contrary to the Petition's repeated reference to the "statutory license" of the URAA, the URAA does not provide anyone, including an ANDA applicant, a "license" to market any product.[8] Nor does the URAA make any conduct "non-infringing". Rather, its plain language applies only to acts which are infringing. Thus, section 154(c)(2)(B) specifically states that it applies only to:

"Acts which --

(B) become *infringing* by reason of . . . ."

35 U.S.C. § 154(c)(2)(B)(emphasis added). When Congress wishes to make acts non-infringing, it knows how to do so in clear and unmistakable terms, as Congress did in the Hatch-Waxman Act when it added section 271(e)(1), which stated: "It shall not be an act of infringement . . . ." 35 U.S.C. § 271(e)(1).

Instead, as is clear from the plain language of the statute, and as the FDA and two different panels of the Federal Circuit have uniformly found, the transition provision of the URAA simply limits certain *remedies* available to certain patent holders in certain types of patent infringement actions. The remedies that "shall not apply" are specifically identified as the "remedies of Sections 283, 284 and 285" of the Patent Code. Clearly, 35 U.S.C. § 154(c) has no impact on an action to redress infringement under 35 U.S.C. § 271(e)(2), the remedies for which are provided by 35 U.S.C. § 271(e)(4). This includes the remedy of section 271(e)(4)(A) which Royce seeks to avoid, *i.e.*, an order that the effective date of ANDA approval be "a date which is not earlier than the date of the expiration of the patent which has been infringed . . . ."

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[8] The URAA nowhere uses the term "license." As the statutes which Royce cited below make clear, Congress knows how to grant a "license" in clear and unmistakable terms when it wishes to do so. *See, e.g.*, 42 U.S.C. § 2183(b)(2) (1988) ("the Commission shall grant such patent license . . ."); 42 U.S.C. § 7608 (1988) (". . . issue an order requiring the person who owns such patent to license it . . .").

Second, Royce and *amici* distort the holding of the lower court, contending that the decision "converts the paragraph IV procedure into a trap which prevents otherwise qualified parties from invoking a statutory license such as that found in the URAA." Pet. at 22. Petitioner suggests that the lower court held that the mere filing of a Paragraph IV certification is an act of infringement sufficient to justify an order that the FDA cannot approve an ANDA prior to the expiration of an applicable patent, whether or not the patent was valid and whether or not it will actually be infringed.

That is simply *not* what the lower court held. To the contrary, the Federal Circuit specifically found that once a Paragraph IV certification is filed, the court must

> determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent. If the court determines that the patent is not invalid and that infringement *would* occur, and that therefore the ANDA applicant's paragraph IV certification is incorrect, the patent owner is entitled to an order that FDA approval of the ANDA containing the paragraph IV certification not be effective until the patent expires.

A-12-13 (emphasis in original). Far from creating a Catch-22 procedural trap, the lower court's decision specifically endorses the need for the very review Royce contends is required.[9]

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9 Here, there is no dispute that Bristol's patent is valid and that it covers Petitioner's generic captopril product. Under the circumstances, it is indisputable that Royce will infringe Bristol's patent if it markets captopril before expiration of the patent. Indeed, the very provision of the URAA on which Royce relies for its alleged "license" confirms that marketing by Royce would infringe Bristol's patent because it specifically relates only to acts that are (or become) "infringing."

The lower court held (correctly) that the "safe harbor" provision of the URAA simply eliminated the remedies of sections 283, 284 and 285 in certain cases. It did not take away the *separate* remedies of section 271(e)(4) which are available to the patentee for an act of infringement under section 271(e)(2) (admitted here) of seeking FDA approval to market a generic product prior to the expiration of a patent.[10] When Congress wishes to take away all remedies, it says so in explicit terms. *Compare* 35 U.S.C. § 287(a) ("no damages shall be recovered"); 35 U.S.C. § 287(b)(2) ("no remedies for infringement . . . shall be available"); 35 U.S.C.A. § 271(g) ("no remedy may be granted"). It did not do so here.

Contrary to the suggestion of Royce and *amici*, there is nothing unusual or puzzling about the fact that Congress did not alter the provisions of the Hatch-Waxman Act. Doing so would have disturbed the delicate balance between the interests of generic and pioneer pharmaceutical companies that are reflected in the Hatch-Waxman Act which created a new and self-contained section -- Section 271(e) -- of the Patent Code.[11] The Hatch-Waxman Act confers on generic drug companies an immunity from infringement given to no other industry -- the freedom to use a patented invention without liability or having to pay compensation in order to develop ANDA applications. If

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[10] The remedies of sections 283, 284 and 285 have no application to the generic drug approval process. "The remedies prescribed by subparagraphs (a), (b) and (c) [of § 271(e)(4)] are the only remedies which may be granted by a court for an act of infringement described in paragraph (2). . . ." 35 U.S.C. § 271(e)(4).

[11] This section abolished traditional acts of infringement with respect to ANDAs (section 271(e)(1)), provided a new act of infringement (section 271(e)(2)) for seeking FDA approval to market generic drug products before the expiration of the applicable patents, and created a new and exclusive set of remedies for that act of infringement (section 271(e)(4)), including the availability of a court order limiting the date of FDA approval (section 271(e)(4)(A)).

Congress had wished to alter this statutory balance, it would have said so explicitly, as both FDA and the lower court recognized.

For the same reason, there is no basis for Royce's claim that the URAA contains a transitional provision whose intended beneficiary must have been the generic drug industry. Pet. at 9. If Congress had intended the transition provision to apply to the generic drug approval process (a contention flatly rejected by both the FDA and the court of appeals), it is inconceivable that it would have failed to include a specific reference to the very statutory provisions, *i.e.*, 35 U.S.C. § 271(e) and 21 U.S.C. § 355(j), it had created expressly to govern that process.

II. THE PETITION DOES NOT PRESENT AN ISSUE OF GENERAL PUBLIC IMPORTANCE

Royce contends that the decision below will have wide-ranging consequences for other products and other parties, affecting the interests of "manufacturers of generic prescription pharmaceuticals," "the American public," and "federal, state and other third-party reimbursement programs." Pet. at 3.

While the decision below is not insignificant, both Royce and *amici* exaggerate its importance. If the issue decided below affects as many products and manufacturers as Royce and *amici* assert, it would already be the subject of a tidal wave of litigation. Significantly, however, neither Royce nor *amici* point to any other litigation. In fact, except for litigation involving Bristol's patented captopril product, there is *no* litigation (of which respondents are aware) that addresses the issue decided below.[12] The absence of

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12 Nor have any third parties (whether generic manufacturers, patented pharmaceutical manufacturers or trade associations) previously participated as *amici*, either in this case or in the *DuPont Merck* case.

comparable litigation concerning any other pharmaceutical product strongly indicates that the issue is neither as significant nor as pressing as the Petition suggests. *Compare Laing v. United States*, 423 U.S. 161, 127 (1976) (70 pending cases in federal court depended on resolution of tax conflict).

Both Royce and *amici* make the unsupported claim that the decision below affects hundreds of drugs. The current litigation position of Royce and *amici* is inconsistent with the prior claim of *amici* that the URAA would have only a minimal effect on the generic industry because "most pharmaceutical patents in effect today took longer than three years to issue. Therefore, switching to the new patent term will provide them no extension of patent term." *Chemical Marketing Reporter*, Jan. 2, 1995, at 4 (quoting Lewis Engman, President, GPIA). Moreover, the generic drug industry has publicly recognized that the result they now seek from this Court would require new legislation to amend the URAA's transition provision to close a "loophole." *See, e.g.*, 141 Cong. Rec. S6495 (daily ed. May 11, 1995) (remarks of Sen. Pryor) cited in Pet. at 9. [13] *See also* 141 Cong. Rec. S12388-12391 (August 11, 1995) (introducing S.1191 to provide that the "remedies of section 271(e)(4) . . . shall not apply to acts" that become infringing as a result of the URAA.)

Royce and *amici* also contend that this Court's review is necessary to correct the decision below which they assert contravenes the clear intent of Congress. However, the intent of Congress is determined first by reference to the

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[13] Similarly, the Corporate Counsel of one of the plaintiffs in the *DuPont Merck* case -- and a principal member of *amicus* National Association of Pharmaceutical Manufacturers -- stated in a presentation to the Food and Drug Law Institute on February 6, 1995 that:

> The GATT implementation language enacted by Congress needs immediate revision prior to its effective date of June 8, 1995.

language which Congress employed in the statute. *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Moreover, neither Royce nor *amici* point to anything in the legislative history of the URAA that would support their claim that Congress intended to do anything other than what the plain language of the statute indicates. *Burlington Northern R.R. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987) ("[I]n the absence of a clearly expressed legislative intention to the contrary, the language of the statute itself must be ordinarily regarded as conclusive'"). In fact, the legislative history supports the lower court's construction of the URAA. Thus, the President's Statement of Administrative Action explains the scope and effect of the limitation of remedies provision of the URAA in exactly the same way in which the FDA and the lower court have construed it: "the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees *as provided for in sections 283 to 285 of Title 35*." H.R. Doc. No. 316, 103d Cong., 2d Sess. 1003 (1994) (emphasis added).

In any event, review is not appropriate because the judgment below was proper even if Royce's interpretation of the URAA's transition provision is correct (which Bristol denies and the Federal Circuit has twice rejected). The statutory "safe harbor" applies only if Royce has made a "substantial investment" in contemplation of acts which "become infringing." 35 U.S.C. § 154(c)(2). It remains to be determined whether Royce satisfies this *factual* predicate to the URAA "safe harbor." While the district court below concluded in a footnote that Royce met the statute's "substantial investment" criterion, that decision was clearly erroneous since the district court improperly accepted the factual assertions contained in an affidavit made in support of a motion to dismiss Bristol's complaint, without permitting Bristol any opportunity to take any discovery on this issue. Because the Federal Circuit found that there was no legal basis to Petitioner's claim, it did not reach the

validity of the district court's decision on the issue of "substantial investment." As a result, a decision by this Court on the issue presented by the Petition may be unnecessary and irrelevant to the disposition of the case below.

CONCLUSION

For all of the foregoing reasons, the Court should deny the Petition.

Respectfully submitted,

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Dated: December 11, 1995

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

May 25, 1995

Donald O. Beers
David E. Korn
Arnold & Porter
1200 New Hampshire Avenue, N.W.
Washington, D.C. 20036

Re: Docket No. 95P-0061/CP1

Dear Messrs. Beers and Korn:

This responds to the citizen petition you submitted on behalf of Glaxo Inc. (Glaxo) dated March 7, 1995.[1] The citizen petition requests that the Food and Drug Administration (FDA) "follow the mandate of the [Uruguay Round Agreements Act (Pub. L. 103-465)] URAA in determining when approval of an Abbreviated New Drug Application ('ANDA') or application of the type described in Section 505(b)(2) of the Federal Food, Drug, and

[1] FDA has received a number of responses to Glaxo's citizen petition from generic and innovator drug manufacturers. Glaxo has submitted an additional comment on the responses dated April 13, 1995. These documents, as well as correspondence referred to in this response, are included in Docket No. 95P-0061. The agency has considered these submissions, as well as the oral and written submissions made in connection with the February 16, 1995, hearing held by the Patent and Trademark Office (PTO) at which these issues were addressed in its response to Glaxo's citizen petition.

Cosmetic Act ('FFDCA'), 21 U.S.C. § 355(b)(2), ('505(b)(2) application'), may be made effective." Citizen Petition at 1. The citizen petition specifically requests that:

(1) FDA publish patent dates as revised by the URAA in "Approved Drug Products With Therapeutic Equivalence Evaluations" (the Orange Book) prior to June 8, 1995;

(2) FDA announce that pending ANDA and 505(b)(2) applications containing paragraph III certifications to the pre-URAA patent expiration dates must be amended to acknowledge the patent expiration dates as extended by the URAA;

(3) FDA announce that any new ANDA's or 505(b)(2) applications must refer to the patent expiration dates extended by the URAA;

(4) FDA not make approvals of any ANDA or 505(b)(2) application containing a paragraph III certification effective prior to the patent expiration date as revised by the URAA; and

(5) FDA require ANDA and 505(b)(2) applicants that seek an effective date of approval prior to the URAA-revised patent expiration date to submit paragraph IV certifications for any applicable patents.

Citizen Petition at 2-3.

For the reasons set out below, the agency grants your citizen petition in part, and denies your citizen petition in part.

I. STATUTORY AND REGULATORY BACKGROUND

The relief sought by the citizen petition filed on behalf of Glaxo must be determined under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the URAA, which establish the obligations of approved new drug application (NDA) holders, ANDA and 505(b)(2) applicants, and the agency with respect to extended expiration dates for patents covering listed drugs or their uses.[2]

A. The FD&C Act and FDA Regulations

The agency's decision in this matter is governed by provisions of the FD&C Act related to new drug and generic drug approvals. These provisions were added to the FD&C Act through the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417) (the Waxman-Hatch Amendments). Title I of the Waxman-Hatch Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H. Rept. No. 857 (Part I), 98th Cong., 2d sess. at 14 (1984) (House Report). Title II of the Waxman-Hatch Amendments was intended to provide a new incentive for increased expenditures for research and development of drug products by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." (House Report at 15.)[3]

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2 This analysis applies as well to abbreviated new animal drug applications (ANDA's), by which manufacturers seek approval to market generic versions of animal drugs under section 512 of the FD&C Act.

3 Until the Waxman-Hatch Amendments, manufacturers of generic versions of pioneer drugs first approved after 1962 generally were required to duplicate the time-consuming and expensive safety and effectiveness studies already performed on the pioneer drugs. The

1. New Drug Applications

Under the Waxman-Hatch Amendments, pharmaceutical companies seeking to market pioneer drugs must first obtain FDA approval through the filing of an NDA (see section 505(a) and (b) of the FD&C Act). In addition to data demonstrating the safety and effectiveness of the drug, an NDA applicant is required to submit to FDA information on any patent which claims the drug or a method of using such drug for which a claim of patent infringement could reasonably be asserted against an unauthorized party (see section 505(b)(1) and (c)(2) of the FD&C Act). The patent information must include the patent number and date of expiration. Id. If patent information is available at the time the NDA is submitted or becomes available during the pendency of FDA's review of the application, it must be included with the NDA or filed in an amendment to the application (see section 505(b)(1) of the FD&C Act).

The statute specifically anticipates that patents may issue after approval of the NDA and provides for submission of information to FDA on those patents (see section 505(c)(2) of the FD&C Act). The Waxman-Hatch Amendments provide for the extension of patent term expiration dates for listed patents under the patent term restoration provisions (see 35 U.S.C. 156).

FDA is to publish the patent information submitted to it by the NDA holder (see section 505(b)(1) and (c)(2) of the FD&C Act). The agency publishes the required patent information in its publication, the Orange Book. When accepting patent information from the NDA sponsor under

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Waxman-Hatch Amendments permit these generic drug manufacturers to rely on FDA's prior determinations of the safety and efficacy of the pioneer drug (see House Report at 14 and 15).

section 505(b)(1) and (c)(2) of the FD&C Act, FDA is acting in a solely ministerial capacity. The agency relies on the sponsor's assessment of the applicability of the patent to the drug and does not make an independent determination on that issue (see the Federal Register of October 3, 1994, 59 FR 50338 at 50343, 50345, 50348, 50349, 50361). The statutory scheme relies on private patent litigation to resolve disputes concerning patent validity and applicability (see 59 FR 50338 at 50348).

Because current patent information is an important part of the patent certification process, patent information that becomes available after approval of the NDA because of the issuance of a new patent or a Waxman-Hatch patent term extension will be published by FDA (see 59 FR 50338 at 50343).

2. ANDA's and 505(b)(2) Applications

A manufacturer that wishes to market a generic version of a pioneer drug must submit to FDA an ANDA (see section 505(a) and (j) of the FD&C Act). An applicant that wishes to gain approval of an application for a new drug when the investigations that show the safety and effectiveness of the drug were not conducted by the applicant and for which the applicant has not obtained a right of reference or use must submit to FDA a 505(b)(2) application (see section 505(a) and (b) of the FD&C Act). The statute requires that an ANDA or 505(b)(2) application contain, among other data and information, a certification with respect to each patent that claims the drug for which the ANDA applicant is seeking approval. This certification must state one of the following:

(I) that the required patent information relating to such patent has not been filed;

(II) that such patent has expired;

(III) that the patent will expire on a particular date; or

(IV) that such patent is invalid or will not be infringed by the drug for which approval is being sought.

(See section 505(b)(2)(A) and (j)(2)(A)(vii) of the FD&C Act.)

The two types of patent certifications particularly relevant in this matter are those made under paragraph III (a paragraph III certification) and paragraph IV (a paragraph IV certification). A paragraph III certification indicates that the applicant does not intend to market the drug until after the expiration date of the applicable patent. An applicant whose ANDA or 505(b)(2) application contains a paragraph IV certification must give notice of the filing to the patent owner and the NDA holder for the listed drug (see section 505(b)(3) and (j)(2)(B) of the FD&C Act). This notice must include a detailed statement of the factual and legal basis for the applicant's opinion that the patent is not valid or will not be infringed. Id.

FDA regulations require that an ANDA or 505(b)(2) applicant amend its patent certification if "at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate" (see 21 CFR 314.94(a)(12)(viii)(C) published at 59 FR 50338 at 50366 and 21 CFR 314.50(i)(6)(iii)(A) published at 59 FR 50338 at 50362).

3. FDA Approval of ANDA's and 505(b)(2) Applications

The timing of FDA's approval of an ANDA or 505(b)(2) application is governed, in part, by the patent certifications submitted by the applicant. FDA may approve

an application that contains a paragraph III certification on the date the patent to which the certification was made expires (see section 505(c)(3)(B) and (j)(4)(B)(II) of the FD&C Act). In the case of a paragraph IV certification, FDA will approve the application, and the approval will become effective immediately despite the unexpired patent, unless an action for infringement of the patent is brought against the applicant within 45 days of the date the patent owner and the NDA holder receive notice of the paragraph IV certification (see section 505(c)(3)(C) and (j)(4)(B)(iii) of the FD&C Act). If a patent action is brought within the 45-day period, FDA may make the approval of the ANDA or 505(b)(2) application effective no earlier (than) 30 months from the date that the patent owner and NDA sponsor received the notice, or such shorter or longer period as the court may order. Id.

B. Uruguary Round Agreements Act

The citizen petition requests that FDA "follow the mandate of the URAA" with respect to approvals of ANDA's and 505(b)(2) applications. Citizen Petition at 1. The URAA was enacted in December 1994 to implement the Uruguary Round Agreements, a series of multilateral agreements, which includes the General Agreement on Tariffs and Trade (GATT) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP's).

URAA's provisions amend Title 35 of the U.S. Code to extend the period of patent protection for some patents. Section 532(a)(1) of the URAA amends 35 U.S.C. 154 to provide that patents issued after June 8, 1995 (the effective date of the patent provisions of URAA), will have a term of 20 years from the date on which the application for the patent was filed or, under certain circumstances, from the date of the earliest patent application filing. Section 532(a)(1) of the URAA also provides that, for patents in

force on June 8, 1995, or that result from an application filed before that date, the patent term shall be the greater of 17 years from the granting of the patent or 20 years from the date on which the application for the patent was filed, or under certain circumstances 20 years from the date of the earliest patent application filing.

The URAA contains a transitional provision governing acts that will become infringing due to the extension of patents in effect or already filed as of June 8, 1995. Section 532(a)(1) of the URAA limits the availability of certain statutory patent infringement remedies for acts that were commenced, or for which substantial investment was made, before June 8, 1995, and which become infringing because of the extension of the patent period.

This provision establishes that the remedies set out in sections 283, 284, and 285 of Title 35, which provide for injunctions, damages, and attorney fees, will not apply to infringing acts during this period. The URAA provides that such infringing acts may be continued upon payment of equitable remuneration to the patentee. The statute does not define "substantial investment" or "equitable remuneration."

The patent code also contains, at 35 U.S.C. 271(e)(4), a provision that establishes the remedies available for infringement of patents on drug products when a manufacturer seeks approval to market a generic version of the drug before the expiration of applicable patents. This section, which provides for a court to order that the effective date of an approval shall be no earlier than the patent expiration date, and for injunctions, damages, and attorney fees, was not among the remedial provisions explicitly made unavailable under the URAA.

Section 271(e) of Title 35 was enacted as part of Title II of the Waxman-Hatch Amendments and relates

specifically to the approval process for generic drug products.[4] Section 271(e)(1) establishes that it is not an act of infringement to use a patented drug for purposes related to obtaining regulatory approval of the product.[5] Section 271(e)(2) states that it shall be an act of infringement to submit a 505(b)(2) application or ANDA "if the purpose of such submission is to obtain approval under [the FD&C Act] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."[6] Section 271(e)(4) lists the remedies available for infringement actions brought under section 271(e)(2), and states that these will be the only remedies for a patent infringement action brought under that provision.

II. PETITIONER'S REQUEST

Petitioner requests that FDA take five specific actions with respect to patents that have expiration dates that will be extended by the URAA. Each of these requests is discussed below.

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4 The patent term extension provisions of the Waxman-Hatch Amendments were also codified in the patent code. 35 U.S.C. 156.

5 This provision essentially overruled the court's decision in Roche Products, Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984) cert. denied, 469 U.S. 856 (1984), that had determined that the use of a patented product even for testing and preparing an application for regulatory approval was an act of infringement.

6 The Supreme Court has observed that section 271(e)(2) creates these "artificial" acts of infringement so that the underlying patent issue can be resolved in a court proceeding pursuant to a paragraph IV certification. Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990). The Court further observes that the remedies of section 271(e)(4) are also artificial remedies. "Quite obviously, the purpose of subsections (e)(2) and (e)(4) is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend." Id.

A. FDA Should Publish Patent Expiration Dates as Revised by the URAA in the Orange Book Before June 8, 1995

The Waxman-Hatch Amendments require that FDA publish the patent information submitted to it in accordance with section 505(b)(1) and (c)(2) of the FD&C Act. The agency publishes patent information submitted to FDA after approval of the NDA when the patent information derives from a patent term extension under 35 U.S.C. 156, or from the issuance of a new patent (see 59 FR 50338 at 50343).

Publication of the URAA-extended patent expiration dates in the Orange Book will assure that ANDA and 505(b)(2) applicants are aware of the patents and patent expiration dates that NDA holders believe apply to the listed drug product or use. This will permit the applicant or another interested party either to provide a corresponding certification in an ANDA or 505(b)(2) application, or to challenge the accuracy of the patent information through the procedures set out in 21 CFR 314.53(f) (published at 59 FR 50364) and 21 CFR 314.94(a)(12)(vii) (published at 59 FR 50365).

FDA denies petitioner's request that the agency publish the URAA-extended patent expiration dates before June 8, 1995. As noted in the citizen petition at p. 10, the new patent expiration dates will take effect on June 8, 1995 (see section 534 of the URAA). The agency will not accept patent information that anticipates the granting of a new patent, a situation analogous to this grant of patent term extension (see the Federal Register of July 10, 1989 (54 FR 28872 at 28908)). This position is consistent with the Waxman-Hatch Amendments' requirement that information on patents be submitted to the agency within 30 days of the date of issue, notwithstanding that patent applicants may receive advance notice that a patent will be issued (see

section 505(c)(2) of the FD&C Act). The agency has stated that, with respect to new patents, the NDA holder may informally notify the agency of the impending issuance of the patent, but that no official action will be taken in response to such notice (see 54 FR 28872 at 28908). This procedure will apply as well with respect to URAA-extended patent expiration dates.[7]

The agency expects to receive information on the URAA-extended patent expiration dates directly from the NDA holder on or after June 8, 1995.[8] The agency will place this information on public display after June 8, 1995, and will publish it in the monthly supplement to the Orange Book after June 8, 1995 (see 21 CFR 314.53(e) published at 59 FR 50364).[9]

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[7] NDA holders that have already submitted information on URAA extended patent terms should resubmit such information on or after June 8, 1995, but before July 8, 1995.

[8] The agency considers the submission of information on URAA-extended patent expiration dates to be analogous to the submission of information on newly issued patents. Information on these URAA-extended patent expiration dates should be submitted to FDA within 30 days of June 8, 1995. PTO stated in the Federal Register of March 27, 1995, that it intends to determine and publish the new expiration dates for patents that (1) will be in force on June 8, 1995, (2) that are entitled to a patent term of 20 years from the date of filing, and (3) that have received patent term extension under the Waxman-Hatch Amendments (see 60 FR 15748). PTO has indicated to FDA that it expects to publish this information before June 8, 1995.

[9] Updated information related to patents on human drug products regulated by the Center for Drug Evaluation and Research will be placed on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, under Docket No. 95S-0117, after June 8, 1995. Updated information related to patents on human drug products regulated by the Center for Biologics Evaluation and Research will be placed on public display in the Dockets Management Branch under Docket No. 95S-0135. Updated information related to patents on animal drug products will be placed on public display in the Dockets Management Branch under

B. FDA Should Announce That Pending ANDA and 505(b)(2) Applications Containing Paragraph III Certifications to the Pre-URAA Patent Expiration Dates Must Be Amended to Acknowledge the URAA-Extended Patent Expiration Dates

FDA's current regulations require that an ANDA or 505(b)(2) applicant amend its patent certification if "at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate" (see 21 CFR 314.94(a)(12)(viii)(C) published at 59 FR 50338 at 50366 and 21 CFR 314.50(i)(6)(iii)(A) published at 59 FR 50338 at 50362). After June 8, 1995, and upon timely submission by the NDA holder of the URAA-extended patent expiration dates, a pending ANDA or 505(b)(2) application that contains a paragraph III certification to the pre-URAA patent expiration date will be inaccurate under the current regulations.

Because the Waxman-Hatch Amendments and implementing regulations require that ANDA and 505(b)(2) applicants certify as to timely patent information, and that the timing of FDA's approval be governed by these certifications, the only way the agency could approve ANDA's and 505(b)(2) applications before the URAA-extended patent expiration date is if the URAA permits FDA to treat the period of extended patent protection granted by the URAA differently than it treats other patent protection asserted by NDA holders. In particular, the agency's actions depend upon whether the URAA permits FDA to make an

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Docket No. 95S-0126. Updated patent information on animal drug products will be published in the monthly supplements to "FDA Approved Animal Drug Products" (the Green Book) after June 8, 1995.

exception to the updated certification requirement for ANDA and 505(b)(2) applications. If applicants are not required to certify to the URAA-extended patent term, FDA may approve the ANDA or 505(b)(2) application upon the expiration of the pre-URAA patent term. Resolution of this issue requires FDA to make a legal judgment concerning the patent code, about which the agency has no special expertise, to determine the applicability of the transitional provisions set out within section 532(a)(1) of the URAA to the generic drug approval process.

Arguably, FDA could treat the periods of URAA-extended patent term differently than it treats other patent protection asserted by NDA holders if the URAA's transitional "grandfather" provision within section 532(a)(1) applied to infringements through ANDA submission and approval. Section 532(a)(1) of the URAA amends 35 U.S.C. 154 to limit the remedies available for infringement, permitting parties that have commenced acts, or made a substantial investment toward acts, which will become infringing under the extended patent period provided by the URAA, to market their products during the URAA-extended period upon payment of "equitable remuneration" to the patentee. The agency cannot find a basis for adopting the interpretation of the URAA that 35 U.S.C. 154, as amended, applies to infringements through ANDA submissions, which are governed by 35 U.S.C. 271(e).

The agency believes that interpretation of the interrelationship between the transitional provisions of section 532(a)(1) of the URAA and 35 U.S.C. 271(e)(4) is governed by the plain language of the URAA. The Supreme Court has established a two-step process for reviewing an agency's interpretation of a statute. Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842 (1984). Under Chevron, the first question is whether Congress has directly addressed the matter at issue. "If the

intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. at 842-43. Only if the statute is silent or ambiguous does the court turn to the second step of the Chevron analysis and determine whether the agency's interpretation of the statute is a permissible one and therefore entitled to deference. Id. at 843-44. In the present matter, the plain meaning of the URAA has determined the agency's position. See United States v. Ron Pair Enterprises, Inc., 489 U.S. 235, 241 (1989) (when language of statute is plain, it is to be enforced according to its terms). The URAA is not "silent or ambiguous" on the question of applying the transitional provision to the generic drug approval process. Indeed, if the statute did admit of more than one interpretation, FDA would have found that approval of pending applications upon the expiration of the pre-URAA patent term for patents issued before June 8, 1995, is more consistent with the underlying goals of the Waxman-Hatch Amendments.

The transitional provision of the URAA limits the remedies available to a patentee in [a] suit brought against an infringer whose actions became infringing due to the URAA patent extension. Section 532 of the URAA specifically lists the three remedial provisions that are unavailable: 35 U.S.C. 283, 284, and 285. This provision does not list among the unavailable remedies section 271(e)(4), which provides for injunctions, damages, and attorney fees for infringement actions arising from a manufacturer seeking approval from FDA to market a generic version of a patented drug product before the patent on the product expires. Moreover, this apparently is not an example of Congress having overlooked a statutory provision it might have changed had it been aware of its existence; section 533 of the URAA amends 35 U.S.C. 271(e)(4) to apply the remedies specified to a broader range of infringing actions (e.g., it extends coverage from "sale" to "offer to sell"). In light of this reference in the

URAA to section 271, the agency does not believe that it can assert that Congress was unaware of the existence of these remedies for infringement of patents on drug products, and, therefore, did not include them among the unavailable remedies in section 532(a)(1) of the URAA.

In the present matter, therefore, the plain meaning of the URAA is dispositive. While the results of this literal interpretation of the words of the statute are puzzling, in that Congress has--without explanation in the legislative history--applied the transitional "grandfathering" provision to every patented product except drugs, the agency believes that this result follows from the language of the statute.[10]

The limited legislative history for section 532 of the URAA does not provide any affirmative support for the argument asserted in responses to the citizen petition that it was Congress' intention to apply the transitional provision to all acts of patent infringement. The language in the TRIP's Agreement permits, but does not require, the inclusion of a transitional provision in the implementing legislation adopted by a member country.[11] The statements contained

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[10] The statutory language is particularly perplexing in light of recent congressional attention to health care costs, and the detrimental effect an extension of patent term protection to innovator companies may have on the availability to private and governmental consumers of lower-cost generic alternatives. These are some of the same concerns that formed a basis for passage of the 1984 Waxman-Hatch Amendments. Indeed, in a March 29, 1995, letter to Commissioner Kessler, Representative Henry Waxman, co-author of the Waxman-Hatch Amendments, notes that "applying the transition provisions to allow the more timely entry of generics onto the market is reflective of the spirit of the [Waxman-Hatch Amendments]." In contrast, Senator Orrin Hatch, also a co-author of the Waxman-Hatch Amendments, indicated in a January 19, 1995, letter to Commissioner Kessler that it is his belief that if the agency were to approve ANDA's upon the expiration of the pre-URAA patent term, it would jeopardize the "careful balance between the interests of the generic and pioneer drug manufacturers."

[11] The TRIP's Agreement provides, at Article 70.4, that:

in the Statement of Administrative Action and in the Joint Senate report are not specific as to the parties affected by the transitional provision and are merely restatements of the general technical aspects of the provision.[12]

> In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases, the Member shall, however, at least provide for the payment of equitable remuneration.

(Emphasis added.) Reprinted in H. Doc. No. 316, 103d Cong., 2d sess. at 1651-1652 (1994) (House Document).

[12] The Statement of Administrative Action that accompanied the URAA states that:

> Section 532(a) also adds sections 154(c)(2) and (3) [to the patent code]. These sections address situations where a third party begins use of a patented invention before the date that is six months after the date of enactment of the Uruguay Round Agreements Act and such use becomes infringing because of a change in patent term due to operation of section 154(c)(1). In such circumstances, the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees as provided for in sections 283 to 285 of Title 35, but will be able to recover equitable remuneration from a third party who infringes the patent during the period in question.

House Document at 1003.

The Joint Report of the Committee on Finance, Agriculture, Nutrition, and Forestry, and Governmental Affairs contains a nearly identical statement:

> Section 532(a) adds new sections 154(c)(2) and (3). These sections address the situation where a third party begins

In a May 19, 1995, letter to Commissioner Kessler, United States Trade Representative Kantor, chief negotiator of the Uruguay Round Agreements, indicated that the intention of the language of the provision was to treat all companies equally. In other words, according to the United States Trade Representative, generic pharmaceutical companies that have made a substantial investment in anticipation of the expiration of the pre-URAA patent should be permitted to market their products as of that date, upon payment of equitable remuneration. This letter indicates that the language of the URAA does not reflect the legislative intent. Nevertheless, the language of the statute is controlling.

For the reasons set out above, the agency has determined that the URAA provides no basis for FDA to treat the period of patent extension furnished by the URAA differently than it treats other patent protection asserted by NDA holders. There is therefore no support for FDA to change its regulation that requires an applicant with a pending ANDA or 505(b)(2) application to amend its certification to respond to patent information filed after the application was submitted but before approval is effective. ANDA and 505(b)(2) applications pending before the agency on June 8, 1995, that contain certifications only with respect to pre-URAA patent expiration dates must be amended to

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using a patented invention anytime during the six months after the enactment of the legislation and such use becomes infringing because of a change in patent term due to the operation of section 154(c)(1). In such circumstances, the patent owner will not be able to obtain an injunction, recover a reasonable royalty, or obtain attorneys fees, but will be able to recover equitable remuneration.

S. Rept. No. 412, 103d Cong., 2d sess. at 228-229 (1994).

respond to URAA-extended patent expiration dates, if such information is submitted in a timely manner by the NDA holder. Applications that do not include certifications amended to respond to the URAA-extended patent expiration dates will not be approved.

C. FDA Should Announce That Any New ANDA's or 505(b)(2) Applications Must Refer to the Patent Expiration Dates Extended by the URAA

The agency has determined that the URAA-extended patent expiration dates submitted to FDA in a timely manner by the NDA holder will be the applicable patent expiration dates with respect to patent certifications under section 505(j)(2)(A)(vii) and (b)(2)(A) of the FD&C Act. This determination applies to new ANDA's and 505(b)(2) applications submitted to FDA after the effective date of the URAA patent extension provisions, as well as to applications pending before the agency on the effective date.

D. FDA Should Not Make Approvals of Any ANDA or 505(b)(2) Application Containing a Paragraph III Certification Effective Before the Patent Expiration Date as Revised by the URAA

As discussed above, the timing of FDA approval of an ANDA or 505(b)(2) application is governed in part by the patent certifications submitted by the applicant. In the case of a paragraph III certification, FDA will make approval of the application effective no earlier than the expiration date of the patent that is the subject of the paragraph III certification. Further, FDA regulations require that an applicant with a pending ANDA or 505(b)(2) application amend the certification to respond to timely patent information--including URAA patent extension

information--filed with the agency after the ANDA was submitted. If an application contains a paragraph III certification only with respect to the pre-URAA expiration date for the patent, FDA will not approve the application because the ANDA or 505(b)(2) application will not contain a certification to patent information submitted by the NDA holder in a timely fashion (see section 505(d)(6) and (j)(3)(J) of the FD&C Act).

E. FDA Should Require ANDA and 505(b)(2) Applicants that Seek an Effective Date of Approval Before the URAA-Revised Patent Expiration Date to Submit Paragraph IV Certifications for Any Applicable Patents

The drug approval process established by the Waxman-Hatch Amendments requires that an ANDA or 505(b)(2) application contain a certification stating the status of patents submitted to FDA by the NDA holder. The only certification that is appropriate if an applicant wishes to challenge such a patent is a paragraph IV certification. The paragraph IV certification is appropriate when the applicant believes that the listed patent is "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (see section 505(b)(2)(A)(iv) and (j)(2)(A)(vii)(IV) of the FD&C Act). A paragraph IV certification is also appropriate when an applicant believes that the patent is unenforceable (see 21 CFR 314.94(a)(12)(i)(A)(4) published at 59 FR 50338 at 50365, 21 CFR 314.50(i)(1)(i)(A)(4) published at 59 FR 50338 at 50361, and 59 FR 50338 at 50339 (discussing Merck v. Danbury Pharmacal, Inc., 694 F. Supp. 1 (D. Del. 1988), aff'd, 873 F.2d 1418 (Fed. Cir. 1989))).

FDA cannot require an ANDA or 505(b)(2) applicant to file a paragraph IV certification with respect to a patent. It can, and will, however, refuse to approve an application that

contains a paragraph III certification to an incorrect patent expiration date, including a certification to the pre-URAA expiration date of a patent for which a URAA-extended patent expiration date has been submitted to the agency in a timely fashion. If an applicant with an incorrect certification wishes to obtain FDA approval of its ANDA or 505(b)(2) application, it must amend its application to provide either a paragraph III certification indicating that it will wait until the URAA-extended patent has expired, or a paragraph IV certification indicating that the patent is invalid, unenforceable, or will not be infringed. As discussed above, if a patent challenge is brought within 45 days by the patent owner or NDA holder, FDA must stay its approval for at least 30 months, unless a shorter or longer time is ordered by a court.[13]

III. CONCLUSION

The 1984 Waxman-Hatch Amendments to the Federal Food, Drug, and Cosmetic Act represent a careful balance between the policies of fostering the availability of generic drugs and of providing sufficient incentives for research on breakthrough drugs. This landmark compromise between the interests of the generic drug companies and the pioneer companies was intended to grant a one-time patent term extension in exchange for the prompt availability of generic drug products. There is certainly a strong argument to be made that such a compromise should not be upset without hearings and careful deliberation as to the impact on the twin interests served by the Waxman-Hatch Amendments.

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[13] The agency is aware that for some applicants, the 30-month stay required of FDA will consume whatever period of marketing the applicant might have gained by obtaining approval upon the expiration of the pre-URAA patent term.

Here there were neither hearings nor a single word of debate on the floor of the House or Senate on the impact of the URAA on the 1984 Waxman-Hatch Amendments. Nor do the committee reports indicate that Congress understood that the URAA would both grant a patent term extension for certain pioneer products and block FDA from approving generic versions of those drugs until the extended patent terms have expired. Nonetheless, the language of the URAA directs that result.

Accordingly, for the reasons stated above, FDA grants your citizen petition in part and denies your citizen petition in part. FDA has determined that the URAA-extended patent term expiration dates will be the governing patent expiration dates with respect to NDA submissions and FDA publication of patent information on listed drugs and their uses; however, FDA will not publish the URAA-extended patent expiration dates until after they become effective on June 8, 1995. ANDA's and 505(b)(2) applications pending before the agency on June 8, 1995, must be amended to respond to the URAA-extended patent expiration dates, if information on the new expiration dates is submitted to the agency in a timely manner. ANDA's and 505(b)(2) applications submitted after June 8, 1995, similarly must provide patent certifications with respect to the URAA-extended patent expiration dates. After June 8, 1995, FDA will not approve any application that does not contain a correct certification with respect to a URAA-extended patent expiration date that was submitted in a timely manner to the agency. Finally, FDA cannot require that an applicant submit a paragraph IV certification as to a certain patent. The agency expects that an ANDA or 505(b)(2) applicant that wishes to market a generic version of a drug prior to the expiration of a URAA-extended patent, for which

information was timely submitted to FDA, will file a paragraph IV certification with respect to that patent.

Sincerely yours,

/s/William B. Schultz
Deputy Commissioner for Policy